**A Study on the Immune Response and Safety of a Multicomponent Shigella Vaccine in Preventing Shigellosis in Infants**

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**Study Results**

## Participant Flow

## Recruitment Details

| Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations |
|---|
| No text entered. |

**Pre-Assignment Details**

| Significant events and approaches for the overall study following participant enrollment, but prior to group assignment |
|---|
| No text entered. |

**Reporting Groups**

| | Description |
|---|---|
| altSonflex1-2-3 Low Dose | Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169. |
| altSonflex1-2-3 Medium Dose | Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| altSonflex1-2-3 High Dose | Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| Control | Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. |

**Participant Flow: Overall Study**

| | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control | Total(Not Public) |
|---|---|---|---|---|---|
| STARTED | 50 | 50 | 50 | 50 | 200 (calculated) |
| COMPLETED | 47 | 42 | 48 | 48 | 185 (calculated) |
| NOT COMPLETED | 3 | 8 | 2 | 2 | 15 (calculated) |
| Lost to Follow-up | 2 | 2 | 0 | 0 | 4 (calculated) |
| Withdrawal by Subject | 1 | 5 | 2 | 2 | 10 (calculated) |
| Not specified | 0 | 1 | 0 | 0 | 1 (calculated) |
| Total( Not Public ) | 3 (calculated) | 8 (calculated) | 2 (calculated) | 2 (calculated) | 15 (calculated) |

## Baseline Characteristics

**Analysis Population Description** -- ***Explanation of how the number of participants for analysis was determined.***

**Reporting Groups**

| | Description |
|---|---|
| altSonflex1-2-3 Low Dose | Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169. |
| altSonflex1-2-3 Medium Dose | Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| altSonflex1-2-3 High Dose | Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| Control | Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. |

**Baseline Measures**

| | | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control | Total |
|---|---|---|---|---|---|---|
| Overall Number of Baseline Participants | | 50 | 50 | 50 | 50 | 200 |
| Age Continuous Mean Unit of measure: Months Mean (Standard Deviation) | | | | | | |
| | Number Analyzed | 50 Participants | 50 Participants | 50 Participants | 50 Participants | 200 *(calculated)* Participants |
| | | 9.3 (0.5) | 9.3 (0.5) | 9.3 (0.5) | 9.3 (0.5) | 9.3 (0.5) |
| Sex: Female, | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Male**<br>**Count of Participants**<br>**Unit of measure: Participants** | | | | | | |
| | **Number Analyzed** | **50 Participants** | **50 Participants** | **50 Participants** | **50 Participants** | **200 Participants** |
| | **Female** | **29** | **21** | **27** | **35** | **112** ***(calculated)*** |
| | **Male** | **21** | **29** | **23** | **15** | **88** ***(calculated)*** |
| **Race/Ethnicity, Customized**<br>**Count of Participants**<br>**Unit of measure: Participants**<br>**BLACK OR AFRICAN AMERICAN** | | | | | | |
| **BLACK OR AFRICAN AMERICAN** | **Number Analyzed** | **50 Participants** | **50 Participants** | **50 Participants** | **50 Participants** | **200 Participants** |
| | | **50** | **50** | **50** | **50** | **200** ***(calculated)*** |

## Outcome Measures

**1. Primary Outcome Measure: Geometric mean concentrations (GMCs) of anti-serotype specific Shigella lipopolysaccharide (LPS)/O-Antigen (OAg) serum immunoglobulin G (IgG) [ Time Frame: At Day 1 (before administration of Dose 1) ]**

| | |
|---|---|
| **Measure Type** | **Geometric Mean** |
| **Measure Name** | **Geometric mean concentrations (GMCs) of anti-serotype specific Shigella lipopolysaccharide (LPS)/O-Antigen (OAg) serum immunoglobulin G (IgG)** |
| **Measure Description** | **Anti-serotype specific Shigella LPS/OAg serum IgG GMCs were measured by enzyme-linked immunosorbent assay (ELISA) and expressed in ELISA units per milliliter (EU/mL) of serum. S. sonnei, S. flexneri 1b, S. flexneri 2a, and S. flexneri 3a serotypes were tested.** |
| **Time Frame** | **At Day 1 (before administration of Dose 1)** |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| **The analysis was performed on the Immunogenicity Set which included all eligible participants who received all doses as per protocol, had immunogenicity results post-dose, complied with dosing/blood draw intervals, without intercurrent conditions that may interfere with immunogenicity and without prohibited concomitant medication/vaccination. Only participants with anti-serotype specific Shigella LPS/OAg serum IgG data available at Day1 were reported in this outcome measure.** |

**Reporting Groups**

| | **Description** |
|---|---|
| **altSonflex1-2-3 Low Dose** | **Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169.** |
| **altSonflex1-2-3 Medium Dose** | **Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.** |

| | |
|---|---|
| altSonflex1-2-3 High Dose | Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| Control | Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. |

**Measured Values**

| | | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|---|
| Overall Number of Participants Analyzed | | 50 | 50 | 50 | 50 |
| Geometric Mean (95% Confidence Interval) [units: ELISA units per milliliter (EU/mL)] | | | | | |
| S. sonnei | Number Analyzed | 50 Participants | 50 Participants | 50 Participants | 50 Participants |
| | | 7.4 (6.5 to 8.3) | 8.1 (7.0 to 9.5) | 8.7 (6.6 to 11.5) | 9.2 (7.3 to 11.7) |
| S. flexneri 1b | Number Analyzed | 50 Participants | 50 Participants | 50 Participants | 50 Participants |
| | | 5.5 (4.4 to 6.9) | 8.3 (5.7 to 12.1) | 7.6 (5.6 to 10.4) | 6.1 (4.7 to 7.9) |
| S. flexneri 2a | Number Analyzed | 50 Participants | 50 Participants | 50 Participants | 50 Participants |
| | | 5.1 (3.8 to 6.9) | 4.9 (3.4 to 7.1) | 4.6 (3.1 to 6.8) | 4.0 (2.9 to 5.6) |
| S. flexneri 3a | Number Analyzed | 50 Participants | 50 Participants | 50 Participants | 50 Participants |
| | | 3.9 (2.9 to 5.2) | 5.1 (3.4 to 7.6) | 4.2 (3.0 to 6.0) | 4.2 (3.0 to 5.7) |

**No statistical analysis provided for Geometric mean concentrations (GMCs) of anti-serotype specific Shigella lipopolysaccharide (LPS)/O-Antigen (OAg) serum immunoglobulin G (IgG)**

**2. Primary Outcome Measure: GMCs of anti-serotype specific Shigella LPS/OAg serum IgG [ Time Frame: At Day 29 (28 days after administration of Dose 1) ]**

| | |
|---|---|
| **Measure Type** | **Geometric Mean** |
| **Measure Name** | **GMCs of anti-serotype specific Shigella LPS/OAg serum IgG** |
| **Measure Description** | |
| **Time Frame** | **At Day 29 (28 days after administration of Dose 1)** |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| **The analysis was performed on the Immunogenicity Set. Only participants with anti-serotype specific Shigella LPS/OAg serum IgG data available at Day 29 were reported in this outcome measure.** |

**Reporting Groups**

| | **Description** |
|---|---|
| **altSonflex1-2-3 Low Dose** | **Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169.** |
| **altSonflex1-2-3 Medium Dose** | **Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.** |
| **altSonflex1-2-3 High Dose** | **Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.** |
| **Control** | **Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169.** |

**Measured Values**

| | | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|---|
| Overall Number of Participants Analyzed | | 48 | 44 | 48 | 48 |
| Geometric Mean (95% Confidence Interval) [units: EU/mL] | | | | | |
| S. sonnei | Number Analyzed | 48 Participants | 44 Participants | 48 Participants | 48 Participants |
| | | 44.6 (32.2 to 61.7) | 66.4 (46.9 to 93.9) | 59.5 (44.7 to 79.1) | 8.7 (7.0 to 10.8) |
| S. flexneri 1b | Number Analyzed | 48 Participants | 44 Participants | 48 Participants | 48 Participants |
| | | 20.2 (13.9 to 29.5) | 48.7 (35.1 to 67.7) | 30.5 (20.4 to 45.6) | 6.5 (4.8 to 8.9) |
| S. flexneri 2a | Number Analyzed | 48 Participants | 44 Participants | 48 Participants | 48 Participants |
| | | 71.3 (43.1 to 117.8) | 98.4 (64.0 to 151.3) | 77.1 (53.8 to 110.5) | 4.5 (3.1 to 6.7) |
| S. flexneri 3a | Number Analyzed | 48 Participants | 44 Participants | 48 Participants | 48 Participants |
| | | 11.0 (7.1 to 16.9) | 24.1 (15.4 to 37.9) | 16.6 (11.2 to 24.6) | 5.2 (3.5 to 7.6) |

No statistical analysis provided for GMCs of anti-serotype specific Shigella LPS/OAg serum IgG

3. Primary Outcome Measure: GMCs of anti-serotype specific Shigella LPS/OAg serum IgG [ Time Frame: At Day 169 (before administration of Dose 2) ]

| Measure Type | Geometric Mean |
|---|---|
| Measure Name | GMCs of anti-serotype specific Shigella LPS/OAg serum IgG |

| | |
|---|---|
| **Measure Description** | |
| **Time Frame** | **At Day 169 (before administration of Dose 2)** |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| **The analysis was performed on the Immunogenicity Set. Only participants with anti-serotype specific Shigella LPS/OAg serum IgG data available at Day 169 were reported in this outcome measure.** |

**Reporting Groups**

| | **Description** |
|---|---|
| **altSonflex1-2-3 Low Dose** | **Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169.** |
| **altSonflex1-2-3 Medium Dose** | **Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.** |
| **altSonflex1-2-3 High Dose** | **Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.** |
| **Control** | **Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169.** |

**Measured Values**

| | **altSonflex1-2-3 Low Dose** | **altSonflex1-2-3 Medium Dose** | **altSonflex1-2-3 High Dose** | **Control** |
|---|---|---|---|---|
| **Overall Number of Participants Analyzed** | **47** | **44** | **45** | **46** |
| **Geometric Mean (95% Confidence Interval) [units: EU/mL]** | | | | |

| | | | | | |
|---|---|---|---|---|---|
| S. sonnei | Number Analyzed | 47 Participants | 44 Participants | 45 Participants | 46 Participants |
| | | 26.0 (16.4 to 41.3) | 34.7 (22.9 to 52.6) | 33.5 (23.3 to 48.3) | 10.6 (7.1 to 15.8) |
| S. flexneri 1b | Number Analyzed | 47 Participants | 44 Participants | 45 Participants | 46 Participants |
| | | 12.0 (8.3 to 17.2) | 16.2 (11.2 to 23.4) | 14.4 (10.0 to 20.9) | 13.2 (9.0 to 19.3) |
| S. flexneri 2a | Number Analyzed | 47 Participants | 44 Participants | 45 Participants | 46 Participants |
| | | 11.2 (7.2 to 17.5) | 13.4 (8.8 to 20.6) | 9.6 (6.2 to 14.8) | 6.0 (4.0 to 8.9) |
| S. flexneri 3a | Number Analyzed | 47 Participants | 44 Participants | 45 Participants | 46 Participants |
| | | 6.0 (4.0 to 9.0) | 10.1 (6.8 to 14.9) | 8.0 (5.4 to 12.0) | 8.4 (5.5 to 12.7) |

No statistical analysis provided for GMCs of anti-serotype specific Shigella LPS/OAg serum IgG

4. Primary Outcome Measure: GMCs of anti-serotype specific Shigella LPS/OAg serum IgG [ Time Frame: At Day 197 (28 days after administration of Dose 2) ]

| | |
|---|---|
| Measure Type | Geometric Mean |
| Measure Name | GMCs of anti-serotype specific Shigella LPS/OAg serum IgG |
| Measure Description | |
| Time Frame | At Day 197 (28 days after administration of Dose 2) |

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The analysis was performed on the Immunogenicity Set. Only participants with anti-serotype specific Shigella LPS/OAg serum IgG data available at Day 197 were reported in this outcome measure.

**Reporting Groups**

| | Description |
|---|---|
| altSonflex1-2-3 Low Dose | Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169. |
| altSonflex1-2-3 Medium Dose | Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| altSonflex1-2-3 High Dose | Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| Control | Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. |

**Measured Values**

| | | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|---|
| Overall Number of Participants Analyzed | | 44 | 42 | 44 | 45 |
| Geometric Mean (95% Confidence Interval) [units: EU/mL] | | | | | |
| S. sonnei | Number Analyzed | 44 Participants | 42 Participants | 44 Participants | 45 Participants |
| | | 802.1 (521.4 to 1234.0) | 1320.3 (903.8 to 1928.8) | 1080.7 (675.7 to 1728.5) | 10.6 (7.2 to 15.6) |
| | Number Analyzed | 44 Participants | 42 Participants | 44 Participants | 45 Participants |

| | | | | | |
|---|---|---|---|---|---|
| S. flexneri 1b | | 32.0 (23.9 to 42.9) | 39.8 (28.3 to 55.9) | 32.3 (22.5 to 46.3) | 12.4 (8.5 to 18.3) |
| S. flexneri 2a | Number Analyzed | 44 Participants | 42 Participants | 44 Participants | 45 Participants |
| | | 83.5 (58.0 to 120.1) | 92.8 (63.7 to 135.1) | 75.3 (52.3 to 108.4) | 5.1 (3.5 to 7.3) |
| S. flexneri 3a | Number Analyzed | 44 Participants | 42 Participants | 44 Participants | 45 Participants |
| | | 19.8 (13.4 to 29.2) | 31.9 (23.0 to 44.3) | 19.1 (12.4 to 29.5) | 7.9 (5.1 to 12.1) |

No statistical analysis provided for GMCs of anti-serotype specific Shigella LPS/OAg serum IgG

5. Primary Outcome Measure: Number of participants with at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG [ Time Frame: At Day 29 compared to baseline (before administration of Dose 1 on Day 1) ]

| | |
|---|---|
| Measure Type | Count of Participants |
| Measure Name | Number of participants with at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG |
| Measure Description | S. sonnei, S. flexneri 1b, S. flexneri 2a, and S. flexneri 3a serotypes were tested. |
| Time Frame | At Day 29 compared to baseline (before administration of Dose 1 on Day 1) |

Population Description

| |
|---|
| Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate. |
| The analysis was performed on the Immunogenicity Set. Only participants with immunogenicity data available for the specified analysis at the specified time points were reported in this outcome measure. |

Reporting Groups

| | Description |
|---|---|
| altSonflex1-2-3 Low Dose | Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169. |
| altSonflex1-2-3 Medium Dose | Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| altSonflex1-2-3 High Dose | Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| Control | Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. |

**Measured Values**

| | | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|---|
| Overall Number of Participants Analyzed | | 48 | 44 | 48 | 48 |
| Count of Participants [units: Participants] | | | | | |
| S. sonnei | Number Analyzed | 48 Participants | 44 Participants | 48 Participants | 48 Participants |
| | | 32 (66.67%) | 31 (70.45%) | 35 (72.92%) | 0 (%) |
| S. flexneri 1b | Number Analyzed | 48 Participants | 44 Participants | 48 Participants | 48 Participants |
| | | 21 (43.75%) | 30 (68.18%) | 27 (56.25%) | 3 (6.25%) |
| S. flexneri 2a | Number Analyzed | 48 Participants | 44 Participants | 48 Participants | 48 Participants |
| | | 37 | 38 | 39 | 3 |

| | | | | | |
|---|---|---|---|---|---|
| | | (77.08%) | (86.36%) | (81.25%) | (6.25%) |
| S. flexneri 3a | Number Analyzed | 48 Participants | 44 Participants | 48 Participants | 48 Participants |
| | | 19<br>(39.58%) | 23<br>(52.27%) | 22<br>(45.83%) | 4<br>(8.33%) |

No statistical analysis provided for Number of participants with at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG

6. Primary Outcome Measure: Number of participants with at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG [ Time Frame: At Day 197 compared to baseline (before administration of Dose 1 on Day 1) ]

| | |
|---|---|
| Measure Type | Count of Participants |
| Measure Name | Number of participants with at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG |
| Measure Description | |
| Time Frame | At Day 197 compared to baseline (before administration of Dose 1 on Day 1) |

Population Description

| |
|---|
| Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate. |
| The analysis was performed on the Immunogenicity Set. Only participants with immunogenicity data available for the specified analysis at the specified time points were reported in this outcome measure. |

Reporting Groups

| | Description |
|---|---|
| altSonflex1-2-3 Low Dose | Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169. |

| | |
|---|---|
| altSonflex1-2-3 Medium Dose | Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| altSonflex1-2-3 High Dose | Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| Control | Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. |

**Measured Values**

| | | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|---|
| Overall Number of Participants Analyzed | | 44 | 42 | 44 | 45 |
| Count of Participants [units: Participants] | | | | | |
| S. sonnei | Number Analyzed | 44 Participants | 42 Participants | 44 Participants | 45 Participants |
| | | 42 (95.45%) | 42 (100%) | 43 (97.73%) | 5 (11.11%) |
| S. flexneri 1b | Number Analyzed | 44 Participants | 42 Participants | 44 Participants | 45 Participants |
| | | 28 (63.64%) | 22 (52.38%) | 22 (50%) | 11 (24.44%) |
| S. flexneri 2a | Number Analyzed | 44 Participants | 42 Participants | 44 Participants | 45 Participants |
| | | 40 (90.91%) | 37 (88.1%) | 37 (84.09%) | 8 (17.78%) |
| S. flexneri 3a | Number Analyzed | 44 Participants | 42 Participants | 44 Participants | 45 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 22<br>(50%) | 24<br>(57.14%) | 27<br>(61.36%) | 12<br>(26.67%) |

**No statistical analysis provided for Number of participants with at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG**

**7. Primary Outcome Measure: Number of participants with at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG [ Time Frame: At Day 197 compared to pre-Dose 2 at Day 169 ]**

| | |
|---|---|
| **Measure Type** | **Count of Participants** |
| **Measure Name** | **Number of participants with at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG** |
| **Measure Description** | |
| **Time Frame** | **At Day 197 compared to pre-Dose 2 at Day 169** |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| **The analysis was performed on the Immunogenicity Set. Only participants with immunogenicity data available for the specified analysis at the specified time points were reported in this outcome measure.** |

**Reporting Groups**

| | **Description** |
|---|---|
| **altSonflex1-2-3 Low Dose** | **Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169.** |
| **altSonflex1-2-3 Medium Dose** | **Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.** |

| | |
|---|---|
| altSonflex1-2-3 High Dose | Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| Control | Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. |

**Measured Values**

| | | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|---|
| Overall Number of Participants Analyzed | | 44 | 42 | 44 | 45 |
| Count of Participants [units: Participants] | | | | | |
| S. sonnei | Number Analyzed | 44 Participants | 42 Participants | 44 Participants | 45 Participants |
| | | 36 (81.82%) | 39 (92.86%) | 41 (93.18%) | 0 (%) |
| S. flexneri 1b | Number Analyzed | 44 Participants | 42 Participants | 44 Participants | 45 Participants |
| | | 13 (29.55%) | 8 (19.05%) | 8 (18.18%) | 1 (2.22%) |
| S. flexneri 2a | Number Analyzed | 44 Participants | 42 Participants | 44 Participants | 45 Participants |
| | | 31 (70.45%) | 30 (71.43%) | 29 (65.91%) | 0 (%) |
| S. flexneri 3a | Number Analyzed | 44 Participants | 42 Participants | 44 Participants | 45 Participants |
| | | 16 (36.36%) | 15 (35.71%) | 7 (15.91%) | 3 (6.67%) |

**No statistical analysis provided for Number of participants with at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG**

**8. Secondary Outcome Measure: Number of participants with solicited administration site events [ Time Frame: During the 7 days after each study intervention administration (study intervention administered at Day 1 and Day 169) ]**

| | |
|---|---|
| **Measure Type** | **Count of Participants** |
| **Measure Name** | **Number of participants with solicited administration site events** |
| **Measure Description** | **The solicited administration site events assessed were erythema, pain and swelling.** |
| **Time Frame** | **During the 7 days after each study intervention administration (study intervention administered at Day 1 and Day 169)** |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| **The analysis was performed on the Exposed Set (ES) which included all participants who received at least 1 dose of the study intervention. Only the participants with solicited administration site events data available for the specified time period were reported in this outcome measure.** |

**Reporting Groups**

| | **Description** |
|---|---|
| **altSonflex1-2-3 Low Dose** | **Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169.** |
| **altSonflex1-2-3 Medium Dose** | **Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.** |
| **altSonflex1-2-3 High Dose** | **Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.** |

| | |
|---|---|
| **Control** | **Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169.** |

**Measured Values**

| | | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|---|
| **Overall Number of Participants Analyzed** | | **50** | **50** | **50** | **50** |
| **Count of Participants [units: Participants]** | | | | | |
| **Erythema, post-Dose 1** | **Number Analyzed** | **50 Participants** | **50 Participants** | **50 Participants** | **50 Participants** |
| | | **7 (14%)** | **6 (12%)** | **6 (12%)** | **3 (6%)** |
| **Erythema, post-Dose 2** | **Number Analyzed** | **48 Participants** | **44 Participants** | **45 Participants** | **49 Participants** |
| | | **3 (6.25%)** | **3 (6.82%)** | **7 (15.56%)** | **4 (8.16%)** |
| **Pain, post-Dose 1** | **Number Analyzed** | **50 Participants** | **50 Participants** | **50 Participants** | **50 Participants** |
| | | **11 (22%)** | **14 (28%)** | **17 (34%)** | **3 (6%)** |
| **Pain, post-Dose 2** | **Number Analyzed** | **48 Participants** | **44 Participants** | **45 Participants** | **49 Participants** |
| | | **11 (22.92%)** | **13 (29.55%)** | **11 (24.44%)** | **13 (26.53%)** |
| **Swelling, post-Dose 1** | **Number Analyzed** | **50 Participants** | **50 Participants** | **50 Participants** | **50 Participants** |

| | | | | | |
|---|---|---|---|---|---|
| | | 7 (14%) | 9 (18%) | 12 (24%) | 2 (4%) |
| Swelling, post-Dose 2 | Number Analyzed | 48 Participants | 44 Participants | 45 Participants | 49 Participants |
| | | 7 (14.58%) | 10 (22.73%) | 7 (15.56%) | 6 (12.24%) |

No statistical analysis provided for Number of participants with solicited administration site events

9. Secondary Outcome Measure: Number of participants with solicited systemic events [ Time Frame: During the 7 days after each study intervention administration (study interventions administered at Day 1 and Day 169) ]

| | |
|---|---|
| Measure Type | Count of Participants |
| Measure Name | Number of participants with solicited systemic events |
| Measure Description | The solicited systemic event assessed was fever (pyrexia). Fever is defined as temperature ≥38.0°Celsius (C), measured axillary. |
| Time Frame | During the 7 days after each study intervention administration (study interventions administered at Day 1 and Day 169) |

Population Description

| |
|---|
| Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate. |
| The analysis was performed on the Exposed Set. Only the participants with solicited systemic events data available for the specified time period were reported in this outcome measure. |

Reporting Groups

| | Description |
|---|---|
| altSonflex1-2-3 Low Dose | Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169. |

| | |
|---|---|
| altSonflex1-2-3 Medium Dose | Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| altSonflex1-2-3 High Dose | Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| Control | Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. |

**Measured Values**

| | | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|---|
| Overall Number of Participants Analyzed | | 50 | 50 | 50 | 50 |
| Count of Participants [units: Participants] | | | | | |
| Fever, post-Dose 1 | Number Analyzed | 50 Participants | 50 Participants | 50 Participants | 50 Participants |
| | | 10 (20%) | 6 (12%) | 9 (18%) | 7 (14%) |
| Fever, post-Dose 2 | Number Analyzed | 48 Participants | 44 Participants | 45 Participants | 49 Participants |
| | | 4 (8.33%) | 10 (22.73%) | 5 (11.11%) | 6 (12.24%) |

**No statistical analysis provided for Number of participants with solicited systemic events**

**10. Secondary Outcome Measure: Number of participants with unsolicited adverse events (AEs) [ Time Frame: During the 28 days after each study intervention administration (study interventions administered at Day 1 and Day 169) ]**

| Measure Type | Count of Participants |
|---|---|

| | |
|---|---|
| Measure Name | Number of participants with unsolicited adverse events (AEs) |
| Measure Description | An unsolicited AE is an AE that was either not included in the list of solicited events or could be included in the list of solicited events but with an onset outside the specified period of follow-up for solicited events. |
| Time Frame | During the 28 days after each study intervention administration (study interventions administered at Day 1 and Day 169) |

**Population Description**

| |
|---|
| Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate. |
| The analysis was performed on the Exposed Set. Only the participants with unsolicited AE data available for the specified time period were reported in this outcome measure. |

**Reporting Groups**

| | Description |
|---|---|
| altSonflex1-2-3 Low Dose | Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169. |
| altSonflex1-2-3 Medium Dose | Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| altSonflex1-2-3 High Dose | Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| Control | Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. |

**Measured Values**

| | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| **Overall Number of Participants Analyzed** | | **50** | **50** | **50** | **50** |
| **Count of Participants [units: Participants]** | | | | | |
| **Unsolicited AEs, post-study intervention administered at Day 1** | **Number Analyzed** | **50 Participants** | **50 Participants** | **50 Participants** | **50 Participants** |
| | | **23 (46%)** | **23 (46%)** | **24 (48%)** | **24 (48%)** |
| **Unsolicited AEs, post-study intervention administered at Day 169** | **Number Analyzed** | **48 Participants** | **44 Participants** | **45 Participants** | **49 Participants** |
| | | **9 (18.75%)** | **14 (31.82%)** | **12 (26.67%)** | **17 (34.69%)** |

**No statistical analysis provided for Number of participants with unsolicited adverse events (AEs)**

**11. Secondary Outcome Measure: Number of participants with serious AEs (SAEs) [ Time Frame: Day 1 to Day 197 ]**

| | |
|---|---|
| **Measure Type** | **Count of Participants** |
| **Measure Name** | **Number of participants with serious AEs (SAEs)** |
| **Measure Description** | **An SAE is defined as any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect in the offspring of a study participant, results in abnormal pregnancy outcomes or any other situation based on appropriate medical or scientific judgement.** |
| **Time Frame** | **Day 1 to Day 197** |

**Population Description**

| Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate. |
|---|
| The analysis was performed on the Exposed Set. Only the participants with SAE data available for the specified time period were reported in this outcome measure. |

**Reporting Groups**

| | Description |
|---|---|
| altSonflex1-2-3 Low Dose | Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169. |
| altSonflex1-2-3 Medium Dose | Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| altSonflex1-2-3 High Dose | Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| Control | Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. |

**Measured Values**

| | | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|---|
| Overall Number of Participants Analyzed | | 50 | 50 | 50 | 50 |
| Count of Participants [units: Participants] | | | | | |
| | Number Analyzed | 50 Participants | 50 Participants | 50 Participants | 50 Participants |
| | | 1 (2%) | 0 (%) | 0 (%) | 0 (%) |

**No statistical analysis provided for Number of participants with serious AEs (SAEs)**

**12. Secondary Outcome Measure: Number of participants with change from baseline in hematological, renal, and hepatic panel test results with respect to laboratory reference ranges at Day 8 [ Time Frame: Day 8 compared to baseline (pre-Dose 1 at Day 1) ]**

| | |
|---|---|
| **Measure Type** | **Count of Participants** |
| **Measure Name** | **Number of participants with change from baseline in hematological, renal, and hepatic panel test results with respect to laboratory reference ranges at Day 8** |
| **Measure Description** | **Panel tests include measures of alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine, potassium, sodium, blood urea, basophils, eosinophils, erythrocytes, hematocrit, hemoglobin, leukocytes, lymphocytes, monocytes, neutrophils and platelets. Categories reported when comparing Day 1 (baseline) and laboratory reference range hematological, renal and hepatic laboratory results are defined as follows: <parameter>,<range at baseline>,<range at timing>, where range is being classified as Below = value below; Within = value within; and Above = value above the laboratory reference range defined for the specified visit and laboratory parameter.** |
| **Time Frame** | **Day 8 compared to baseline (pre-Dose 1 at Day 1)** |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| **The analysis was performed on the Exposed Set. Only the participants with haematological, renal, and hepatic panel test data available at Day 8 were reported in this outcome measure.** |

**Reporting Groups**

| | Description |
|---|---|
| **altSonflex1-2-3 Low Dose** | **Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169.** |
| **altSonflex1-2-3 Medium Dose** | **Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.** |

| | |
|---|---|
| altSonflex1-2-3 High Dose | Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| Control | Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. |

**Measured Values**

| | | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|---|
| Overall Number of Participants Analyzed | | 49 | 46 | 50 | 49 |
| Count of Participants [units: Participants] | | | | | |
| ALT, Below, Below | Number Analyzed | 49 Participants | 46 Participants | 50 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 1 (2%) | 0 (%) |
| ALT, Below, Within | Number Analyzed | 49 Participants | 46 Participants | 50 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| ALT, Below, Above | Number Analyzed | 49 Participants | 46 Participants | 50 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| ALT, Within, Below | Number Analyzed | 49 Participants | 46 Participants | 50 Participants | 49 Participants |
| | | 0 (%) | 1 (2.17%) | 0 (%) | 0 (%) |

| | | | | | |
|---|---|---|---|---|---|
| **ALT, Within, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **48 (97.96%)** | **43 (93.48%)** | **47 (94%)** | **47 (95.92%)** |
| **ALT, Within, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **1 (2.17%)** | **1 (2%)** | **1 (2.04%)** |
| **ALT, Above, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **ALT, Above, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **1 (2.17%)** | **1 (2%)** | **1 (2.04%)** |
| **ALT, Above, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **AST, Below, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **AST, Below, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |

| | | | | | |
|---|---|---|---|---|---|
| **AST, Below, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **AST, Within, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **AST, Within, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **48 (97.96%)** | **45 (97.83%)** | **50 (100%)** | **48 (97.96%)** |
| **AST, Within, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **1 (2.04%)** |
| **AST, Above, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **AST, Above, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **1 (2.17%)** | **0 (%)** | **0 (%)** |
| **AST, Above, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **0 (%)** | **0 (%)** | **0 (%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Creatinine, Below, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **49 (100%)** | **46 (100%)** | **50 (100%)** | **49 (100%)** |
| **Creatinine, Below, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Creatinine, Below, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Creatinine, Within, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Creatinine, Within, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Creatinine, Within, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Creatinine, Above, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Creatinine, Above, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Creatinine, Above, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Potassium, Below, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Potassium, Below, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Potassium, Below, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Potassium, Within, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Potassium, Within, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **48 (97.96%)** | **46 (100%)** | **50 (100%)** | **49 (100%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Potassium, Within, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Potassium, Above, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Potassium, Above, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Potassium, Above, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Sodium, Below, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Sodium, Below, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **1 (2.17%)** | **0 (%)** | **0 (%)** |
| **Sodium, Below, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Sodium, Within, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **1 (2.17%)** | **0 (%)** | **0 (%)** |
| **Sodium, Within, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **31 (63.27%)** | **35 (76.09%)** | **37 (74%)** | **35 (71.43%)** |
| **Sodium, Within, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **10 (20.41%)** | **6 (13.04%)** | **7 (14%)** | **6 (12.24%)** |
| **Sodium, Above, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Sodium, Above, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **4 (8.16%)** | **3 (6.52%)** | **6 (12%)** | **5 (10.2%)** |
| **Sodium, Above, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **3 (6.12%)** | **0 (%)** | **0 (%)** | **3 (6.12%)** |
| **Urea, Below, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **23 (46.94%)** | **29 (63.04%)** | **20 (40%)** | **24 (48.98%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Urea, Below, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **11 (22.45%)** | **1 (2.17%)** | **7 (14%)** | **7 (14.29%)** |
| **Urea, Below, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Urea, Within, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **6 (12.24%)** | **6 (13.04%)** | **10 (20%)** | **10 (20.41%)** |
| **Urea, Within, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **9 (18.37%)** | **9 (19.57%)** | **13 (26%)** | **8 (16.33%)** |
| **Urea, Within, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **1 (2.17%)** | **0 (%)** | **0 (%)** |
| **Urea, Above, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Urea, Above, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Urea, Above, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Basophils, Below, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Basophils, Below, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Basophils, Below, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Basophils, Within, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Basophils, Within, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **27 (55.1%)** | **28 (60.87%)** | **33 (66%)** | **32 (65.31%)** |
| **Basophils, Within, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **3 (6.12%)** | **6 (13.04%)** | **4 (8%)** | **4 (8.16%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Basophils, Above, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Basophils, Above, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **11 (22.45%)** | **8 (17.39%)** | **9 (18%)** | **8 (16.33%)** |
| **Basophils, Above, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **8 (16.33%)** | **4 (8.7%)** | **4 (8%)** | **5 (10.2%)** |
| **Eosinophils, Below, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Eosinophils, Below, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **0 (%)** | **1 (2%)** | **0 (%)** |
| **Eosinophils, Below, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Eosinophils, Within, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **2 (4.08%)** | **3 (6.52%)** | **0 (%)** | **0 (%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Eosinophils, Within, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **40 (81.63%)** | **40 (86.96%)** | **48 (96%)** | **45 (91.84%)** |
| **Eosinophils, Within, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **2 (4.08%)** | **1 (2.17%)** | **0 (%)** | **2 (4.08%)** |
| **Eosinophils, Above, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Eosinophils, Above, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **3 (6.12%)** | **0 (%)** | **0 (%)** | **1 (2.04%)** |
| **Eosinophils, Above, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **2 (4.35%)** | **1 (2%)** | **1 (2.04%)** |
| **Erythrocytes, Below, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Erythrocytes, Below, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Erythrocytes, Below, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Erythrocytes, Within, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **1 (2.17%)** | **0 (%)** | **1 (2.04%)** |
| **Erythrocytes, Within, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **25 (51.02%)** | **28 (60.87%)** | **28 (56%)** | **29 (59.18%)** |
| **Erythrocytes, Within, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **7 (14.29%)** | **3 (6.52%)** | **4 (8%)** | **3 (6.12%)** |
| **Erythrocytes, Above, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Erythrocytes, Above, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **6 (13.04%)** | **6 (12%)** | **4 (8.16%)** |
| **Erythrocytes, Above, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **15 (30.61%)** | **8 (17.39%)** | **12 (24%)** | **12 (24.49%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Hematocrit, Below, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **1 (2%)** | **1 (2.04%)** |
| **Hematocrit, Below, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **2 (4.08%)** | **3 (6.52%)** | **0 (%)** | **3 (6.12%)** |
| **Hematocrit, Below, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Hematocrit, Within, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **3 (6.52%)** | **0 (%)** | **0 (%)** |
| **Hematocrit, Within, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **38 (77.55%)** | **36 (78.26%)** | **38 (76%)** | **34 (69.39%)** |
| **Hematocrit, Within, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **6 (12.24%)** | **0 (%)** | **5 (10%)** | **4 (8.16%)** |
| **Hematocrit, Above, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Hematocrit, Above, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **1 (2.17%)** | **3 (6%)** | **4 (8.16%)** |
| **Hematocrit, Above, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **3 (6.52%)** | **3 (6%)** | **3 (6.12%)** |
| **Hemoglobin, Below, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **5 (10.2%)** | **3 (6.52%)** | **4 (8%)** | **2 (4.08%)** |
| **Hemoglobin, Below, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **3 (6.52%)** | **2 (4%)** | **4 (8.16%)** |
| **Hemoglobin, Below, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Hemoglobin, Within, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **4 (8.7%)** | **1 (2%)** | **1 (2.04%)** |
| **Hemoglobin, Within, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **40 (81.63%)** | **32 (69.57%)** | **37 (74%)** | **38 (77.55%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Hemoglobin, Within, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **1 (2.17%)** | **2 (4%)** | **2 (4.08%)** |
| **Hemoglobin, Above, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Hemoglobin, Above, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **2 (4.35%)** | **2 (4%)** | **2 (4.08%)** |
| **Hemoglobin, Above, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **1 (2.17%)** | **2 (4%)** | **0 (%)** |
| **Leukocytes, Below, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **3 (6%)** | **1 (2.04%)** |
| **Leukocytes, Below, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **2 (4.35%)** | **3 (6%)** | **2 (4.08%)** |
| **Leukocytes, Below, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Leukocytes, Within, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **4 (8.16%)** | **1 (2.17%)** | **1 (2%)** | **2 (4.08%)** |
| **Leukocytes, Within, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **31 (63.27%)** | **30 (65.22%)** | **31 (62%)** | **33 (67.35%)** |
| **Leukocytes, Within, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **3 (6.12%)** | **4 (8.7%)** | **4 (8%)** | **1 (2.04%)** |
| **Leukocytes, Above, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Leukocytes, Above, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **5 (10.2%)** | **9 (19.57%)** | **4 (8%)** | **7 (14.29%)** |
| **Leukocytes, Above, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **5 (10.2%)** | **0 (%)** | **4 (8%)** | **3 (6.12%)** |
| **Lymphocytes, Below, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Lymphocytes, Below, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Lymphocytes, Below, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Lymphocytes, Within, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Lymphocytes, Within, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **30 (61.22%)** | **30 (65.22%)** | **26 (52%)** | **33 (67.35%)** |
| **Lymphocytes, Within, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **5 (10.2%)** | **3 (6.52%)** | **8 (16%)** | **5 (10.2%)** |
| **Lymphocytes, Above, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Lymphocytes, Above, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **6 (12.24%)** | **6 (13.04%)** | **7 (14%)** | **6 (12.24%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Lymphocytes, Above, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **8 (16.33%)** | **7 (15.22%)** | **9 (18%)** | **5 (10.2%)** |
| **Monocytes, Below, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **1 (2.17%)** | **0 (%)** | **0 (%)** |
| **Monocytes, Below, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **2 (4.08%)** | **3 (6.52%)** | **0 (%)** | **4 (8.16%)** |
| **Monocytes, Below, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Monocytes, Within, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **0 (%)** | **1 (2%)** | **1 (2.04%)** |
| **Monocytes, Within, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **27 (55.1%)** | **29 (63.04%)** | **39 (78%)** | **27 (55.1%)** |
| **Monocytes, Within, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **12 (24.49%)** | **8 (17.39%)** | **6 (12%)** | **11 (22.45%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Monocytes, Above, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Monocytes, Above, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **2 (4.08%)** | **2 (4.35%)** | **3 (6%)** | **4 (8.16%)** |
| **Monocytes, Above, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **5 (10.2%)** | **3 (6.52%)** | **1 (2%)** | **2 (4.08%)** |
| **Neutrophils, Below, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **3 (6.12%)** | **3 (6.52%)** | **2 (4%)** | **7 (14.29%)** |
| **Neutrophils, Below, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **4 (8.16%)** | **6 (13.04%)** | **2 (4%)** | **3 (6.12%)** |
| **Neutrophils, Below, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Neutrophils, Within, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **10 (20.41%)** | **1 (2.17%)** | **8 (16%)** | **6 (12.24%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Neutrophils, Within, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **31 (63.27%)** | **33 (71.74%)** | **35 (70%)** | **33 (67.35%)** |
| **Neutrophils, Within, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1 (2.04%)** | **1 (2.17%)** | **1 (2%)** | **0 (%)** |
| **Neutrophils, Above, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Neutrophils, Above, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **2 (4.35%)** | **2 (4%)** | **0 (%)** |
| **Neutrophils, Above, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Platelets, Below, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Platelets, Below, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **1 (2%)** | **0 (%)** |

| | | | | | |
|---|---|---|---|---|---|
| **Platelets, Below, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Platelets, Within, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Platelets, Within, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **7 (14.29%)** | **5 (10.87%)** | **10 (20%)** | **24 (48.98%)** |
| **Platelets, Within, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **9 (18.37%)** | **7 (15.22%)** | **8 (16%)** | **3 (6.12%)** |
| **Platelets, Above, Below** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0 (%)** | **0 (%)** | **0 (%)** | **0 (%)** |
| **Platelets, Above, Within** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **8 (16.33%)** | **10 (21.74%)** | **2 (4%)** | **11 (22.45%)** |
| **Platelets, Above, Above** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **25 (51.02%)** | **24 (52.17%)** | **29 (58%)** | **11 (22.45%)** |

**No statistical analysis provided for Number of participants with change from baseline in hematological, renal, and hepatic panel test results with respect to laboratory reference ranges at Day 8**

**13. Secondary Outcome Measure: Number of participants with change from baseline in hematological, renal, and hepatic panel test results with respect to laboratory reference ranges at Day 176 [ Time Frame: Day 176 compared to pre-Dose 2 at Day 169 ]**

| | |
|---|---|
| **Measure Type** | **Count of Participants** |
| **Measure Name** | **Number of participants with change from baseline in hematological, renal, and hepatic panel test results with respect to laboratory reference ranges at Day 176** |
| **Measure Description** | **Panel tests include measures of alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine, potassium, sodium, blood urea, basophils, eosinophils, erythrocytes, hematocrit, hemoglobin, leukocytes, lymphocytes, monocytes, neutrophils and platelets. Categories reported when comparing Day 169 (baseline) and laboratory reference range hematological, renal and hepatic laboratory results are defined as follows: <parameter>,<range at baseline>,<range at timing>, where range is being classified as Below = value below; Within = value within; and Above = value above the laboratory reference range defined for the specified visit and laboratory parameter.** |
| **Time Frame** | **Day 176 compared to pre-Dose 2 at Day 169** |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| **The analysis was performed on the Exposed Set. Only the participants with haematological, renal, and hepatic panel test data available at Day 176 were reported in this outcome measure.** |

**Reporting Groups**

| | **Description** |
|---|---|
| **altSonflex1-2-3 Low Dose** | **Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169.** |

| | |
|---|---|
| altSonflex1-2-3 Medium Dose | Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| altSonflex1-2-3 High Dose | Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| Control | Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. |

**Measured Values**

| | | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|---|
| Overall Number of Participants Analyzed | | 46 | 43 | 46 | 49 |
| Count of Participants [units: Participants] | | | | | |
| ALT, Below, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 1 (2.33%) | 1 (2.17%) | 0 (%) |
| ALT, Below, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| ALT, Below, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| ALT, Within, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| ALT, Within, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 44 (95.65%) | 42 (97.67%) | 44 (95.65%) | 46 (93.88%) |
| ALT, Within, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 (2.17%) | 0 (%) | 0 (%) | 1 (2.04%) |
| ALT, Above, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| ALT, Above, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 1 (2.04%) |
| ALT, Above, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 (2.17%) | 0 (%) | 1 (2.17%) | 1 (2.04%) |
| AST, Below, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| AST, Below, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| AST, Below, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| AST, Within, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| AST, Within, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 43 (93.48%) | 41 (95.35%) | 45 (97.83%) | 47 (95.92%) |
| AST, Within, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 1 (2.04%) |
| AST, Above, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| AST, Above, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 (2.17%) | 2 (4.65%) | 0 (%) | 0 (%) |
| AST, Above, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 2 (4.35%) | 0 (%) | 1 (2.17%) | 1 (2.04%) |
| Creatinine, Below, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 45 (97.83%) | 43 (100%) | 45 (97.83%) | 47 (95.92%) |
| Creatinine, Below, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 1 (2.17%) | 1 (2.04%) |
| Creatinine, Below, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 (2.17%) | 0 (%) | 0 (%) | 0 (%) |
| Creatinine, Within, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 1 (2.04%) |
| Creatinine, Within, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Creatinine, Within, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Creatinine, Above, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Creatinine, Above, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Creatinine, Above, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Potassium, Below, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Potassium, Below, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Potassium, Below, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Potassium, Within, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Potassium, Within, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 11<br>(23.91%) | 11<br>(25.58%) | 6<br>(13.04%) | 17<br>(34.69%) |
| Potassium, Within, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 9<br>(19.57%) | 10<br>(23.26%) | 14<br>(30.43%) | 13<br>(26.53%) |
| Potassium, Above, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0<br>(%) | 0<br>(%) | 0<br>(%) | 0<br>(%) |
| Potassium, Above, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 9<br>(19.57%) | 6<br>(13.95%) | 6<br>(13.04%) | 2<br>(4.08%) |
| Potassium, Above, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 17<br>(36.96%) | 16<br>(37.21%) | 20<br>(43.48%) | 17<br>(34.69%) |
| Sodium, Below, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0<br>(%) | 0<br>(%) | 0<br>(%) | 0<br>(%) |
| Sodium, Below, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0<br>(%) | 0<br>(%) | 0<br>(%) | 0<br>(%) |
| Sodium, Below, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Sodium, Within, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Sodium, Within, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 37 (80.43%) | 38 (88.37%) | 40 (86.96%) | 39 (79.59%) |
| Sodium, Within, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 6 (13.04%) | 3 (6.98%) | 2 (4.35%) | 2 (4.08%) |
| Sodium, Above, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Sodium, Above, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 3 (6.52%) | 2 (4.65%) | 4 (8.7%) | 8 (16.33%) |
| Sodium, Above, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Urea, Below, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 17 (36.96%) | 17 (39.53%) | 16 (34.78%) | 19 (38.78%) |
| Urea, Below, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 11 (23.91%) | 4 (9.3%) | 9 (19.57%) | 11 (22.45%) |
| Urea, Below, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Urea, Within, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 7 (15.22%) | 4 (9.3%) | 6 (13.04%) | 10 (20.41%) |
| Urea, Within, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 11 (23.91%) | 18 (41.86%) | 15 (32.61%) | 9 (18.37%) |
| Urea, Within, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Urea, Above, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Urea, Above, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Urea, Above, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Basophils, Below, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Basophils, Below, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Basophils, Below, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Basophils, Within, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 (2.17%) | 0 (%) | 0 (%) | 0 (%) |
| Basophils, Within, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 39 (84.78%) | 37 (86.05%) | 43 (93.48%) | 45 (91.84%) |
| Basophils, Within, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 2 (4.35%) | 2 (4.65%) | 1 (2.17%) | 2 (4.08%) |
| Basophils, Above, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Basophils, Above, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 (2.17%) | 2 (4.65%) | 2 (4.35%) | 1 (2.04%) |
| Basophils, Above, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 3 (6.52%) | 2 (4.65%) | 0 (%) | 1 (2.04%) |
| Eosinophils, Below, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Eosinophils, Below, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 1 (2.33%) | 0 (%) | 1 (2.04%) |
| Eosinophils, Below, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Eosinophils, Within, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 0 (%) | 2 (4.65%) | 0 (%) | 0 (%) |
| Eosinophils, Within, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 38 (82.61%) | 29 (67.44%) | 40 (86.96%) | 39 (79.59%) |
| Eosinophils, Within, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 2 (4.35%) | 2 (4.65%) | 4 (8.7%) | 2 (4.08%) |
| Eosinophils, Above, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Eosinophils, Above, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 2 (4.35%) | 0 (%) | 1 (2.17%) | 5 (10.2%) |
| Eosinophils, Above, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 4 (8.7%) | 9 (20.93%) | 1 (2.17%) | 2 (4.08%) |
| Erythrocytes, Below, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Erythrocytes, Below, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Erythrocytes, Below, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Erythrocytes, Within, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Erythrocytes, Within, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 29 (63.04%) | 31 (72.09%) | 28 (60.87%) | 28 (57.14%) |
| Erythrocytes, Within, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 2 (4.35%) | 3 (6.98%) | 3 (6.52%) | 2 (4.08%) |
| Erythrocytes, Above, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Erythrocytes, Above, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 3 (6.52%) | 3 (6.98%) | 5 (10.87%) | 6 (12.24%) |
| Erythrocytes, Above, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 12 (26.09%) | 6 (13.95%) | 10 (21.74%) | 13 (26.53%) |
| Hematocrit, Below, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 1 (2.17%) | 1 (2.04%) |
| Hematocrit, Below, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 1 (2.33%) | 2 (4.35%) | 1 (2.04%) |
| Hematocrit, Below, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Hematocrit, Within, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 (2.17%) | 1 (2.33%) | 1 (2.17%) | 1 (2.04%) |
| Hematocrit, Within, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 32 (69.57%) | 36 (83.72%) | 33 (71.74%) | 33 (67.35%) |
| Hematocrit, Within, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 4 (8.7%) | 2 (4.65%) | 3 (6.52%) | 3 (6.12%) |
| Hematocrit, Above, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Hematocrit, Above, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 2 (4.35%) | 1 (2.33%) | 4 (8.7%) | 6 (12.24%) |
| Hematocrit, Above, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 7 (15.22%) | 2 (4.65%) | 2 (4.35%) | 4 (8.16%) |
| Hemoglobin, Below, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 2 (4.35%) | 6 (13.95%) | 4 (8.7%) | 6 (12.24%) |
| Hemoglobin, Below, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 (2.17%) | 1 (2.33%) | 2 (4.35%) | 1 (2.04%) |
| Hemoglobin, Below, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Hemoglobin, Within, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 1 (2.33%) | 1 (2.17%) | 1 (2.04%) |
| Hemoglobin, Within, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 35 (76.09%) | 31 (72.09%) | 38 (82.61%) | 35 (71.43%) |
| Hemoglobin, Within, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 2 (4.35%) | 1 (2.33%) | 1 (2.17%) | 2 (4.08%) |
| Hemoglobin, Above, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Hemoglobin, Above, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 4 (8.7%) | 2 (4.65%) | 0 (%) | 1 (2.04%) |
| Hemoglobin, Above, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 2 (4.35%) | 1 (2.33%) | 0 (%) | 3 (6.12%) |
| Leukocytes, Below, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 1 (2.33%) | 0 (%) | 1 (2.04%) |
| Leukocytes, Below, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 (2.17%) | 2 (4.65%) | 4 (8.7%) | 2 (4.08%) |
| Leukocytes, Below, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Leukocytes, Within, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 (2.17%) | 0 (%) | 0 (%) | 0 (%) |
| Leukocytes, Within, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 30 (65.22%) | 32 (74.42%) | 28 (60.87%) | 40 (81.63%) |
| Leukocytes, Within, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 4 (8.7%) | 3 (6.98%) | 6 (13.04%) | 3 (6.12%) |
| Leukocytes, Above, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Leukocytes, Above, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 5 (10.87%) | 2 (4.65%) | 3 (6.52%) | 1 (2.04%) |
| Leukocytes, Above, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 5 (10.87%) | 3 (6.98%) | 5 (10.87%) | 2 (4.08%) |
| Lymphocytes, Below, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Lymphocytes, Below, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Lymphocytes, Below, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Lymphocytes, Within, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Lymphocytes, Within, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 28 (60.87%) | 33 (76.74%) | 25 (54.35%) | 35 (71.43%) |
| Lymphocytes, Within, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 7 (15.22%) | 3 (6.98%) | 7 (15.22%) | 9 (18.37%) |
| Lymphocytes, Above, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Lymphocytes, Above, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 2 (4.35%) | 2 (4.65%) | 4 (8.7%) | 2 (4.08%) |
| Lymphocytes, Above, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 9 (19.57%) | 5 (11.63%) | 10 (21.74%) | 3 (6.12%) |
| Monocytes, Below, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Monocytes, Below, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Monocytes, Below, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Monocytes, Within, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Monocytes, Within, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 36 (78.26%) | 36 (83.72%) | 38 (82.61%) | 42 (85.71%) |
| Monocytes, Within, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 3 (6.52%) | 3 (6.98%) | 3 (6.52%) | 5 (10.2%) |
| Monocytes, Above, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Monocytes, Above, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 7 (15.22%) | 1 (2.33%) | 4 (8.7%) | 2 (4.08%) |
| Monocytes, Above, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 3 (6.98%) | 1 (2.17%) | 0 (%) |
| Neutrophils, Below, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 2 (4.35%) | 2 (4.65%) | 3 (6.52%) | 0 (%) |
| Neutrophils, Below, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 4 (8.7%) | 3 (6.98%) | 0 (%) | 7 (14.29%) |
| Neutrophils, Below, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Neutrophils, Within, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 2<br>(4.35%) | 6<br>(13.95%) | 2<br>(4.35%) | 2<br>(4.08%) |
| Neutrophils, Within, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 35<br>(76.09%) | 32<br>(74.42%) | 40<br>(86.96%) | 38<br>(77.55%) |
| Neutrophils, Within, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0<br>(%) | 0<br>(%) | 0<br>(%) | 1<br>(2.04%) |
| Neutrophils, Above, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0<br>(%) | 0<br>(%) | 0<br>(%) | 0<br>(%) |
| Neutrophils, Above, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 3<br>(6.52%) | 0<br>(%) | 1<br>(2.17%) | 1<br>(2.04%) |
| Neutrophils, Above, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0<br>(%) | 0<br>(%) | 0<br>(%) | 0<br>(%) |
| Platelets, Below, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0<br>(%) | 0<br>(%) | 0<br>(%) | 0<br>(%) |
| Platelets, Below, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Platelets, Below, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 (2.17%) | 1 (2.33%) | 1 (2.17%) | 0 (%) |
| Platelets, Within, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Platelets, Within, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 7 (15.22%) | 5 (11.63%) | 6 (13.04%) | 20 (40.82%) |
| Platelets, Within, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 10 (21.74%) | 6 (13.95%) | 12 (26.09%) | 12 (24.49%) |
| Platelets, Above, Below | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 (%) | 0 (%) | 0 (%) | 0 (%) |
| Platelets, Above, Within | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 3 (6.52%) | 4 (9.3%) | 3 (6.52%) | 3 (6.12%) |
| Platelets, Above, Above | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |

| | | | | | |
|---|---|---|---|---|---|
| | | 25<br>(54.35%) | 27<br>(62.79%) | 24<br>(52.17%) | 14<br>(28.57%) |

**No statistical analysis provided for Number of participants with change from baseline in hematological, renal, and hepatic panel test results with respect to laboratory reference ranges at Day 176**

**14. Secondary Outcome Measure: The number of participants with abnormal hematological, renal, and hepatic panel test results by Grade values at Day 8 versus baseline (Day 1) Grade values [ Time Frame: Day 8 compared to baseline (before administration of Dose 1 at Day 1) ]**

| | |
|---|---|
| **Measure Type** | **Number** |
| **Measure Name** | **The number of participants with abnormal hematological, renal, and hepatic panel test results by Grade values at Day 8 versus baseline (Day 1) Grade values** |
| **Measure Description** | **Panel tests include measures of ALT, AST, creatinine, hemoglobin, neutrophils decrease, platelets decrease and white blood cells (WBC) decrease. Categories reported when comparing Day 1 (baseline) and laboratory reference range hematological, renal and hepatic laboratory results are defined as follows: <parameter>,<grade at baseline>,<grade at timing>, where Grade 0=within reference range, Grade 1= mild, Grade 2=moderate, Grade 3=severe and Grade 4=potentially life threatening laboratory abnormality.** |
| **Time Frame** | **Day 8 compared to baseline (before administration of Dose 1 at Day 1)** |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| **The analysis was performed on the Exposed Set. Only the participants with haematological , renal, and hepatic panel test data available at Day 8 were reported in this outcome measure.** |

**Reporting Groups**

| | **Description** |
|---|---|

| | |
|---|---|
| altSonflex1-2-3 Low Dose | Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169. |
| altSonflex1-2-3 Medium Dose | Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| altSonflex1-2-3 High Dose | Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| Control | Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. |

**Measured Values**

| | | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|---|
| Overall Number of Participants Analyzed | | 49 | 46 | 50 | 49 |
| Number [units: Participants] | | | | | |
| ALT, Grade 0, Grade 0 | Number Analyzed | 49 Participants | 46 Participants | 50 Participants | 49 Participants |
| | | 49 | 45 | 50 | 48 |
| ALT, Grade 0, Grade 1 | Number Analyzed | 49 Participants | 46 Participants | 50 Participants | 49 Participants |
| | | 0 | 1 | 0 | 1 |
| AST, Grade 0, Grade 0 | Number Analyzed | 49 Participants | 46 Participants | 50 Participants | 49 Participants |
| | | 49 | 46 | 50 | 49 |
| Creatinine, Grade 0, Grade 0 | Number Analyzed | 49 Participants | 46 Participants | 50 Participants | 49 Participants |
| | | 49 | 46 | 50 | 49 |

| | | | | | |
|---|---|---|---|---|---|
| **Hemoglobin, Grade 0, Grade 0** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **42** | **36** | **43** | **42** |
| **Hemoglobin, Grade 0, Grade 1** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1** | **4** | **1** | **1** |
| **Hemoglobin, Grade 1, Grade 0** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1** | **3** | **2** | **4** |
| **Hemoglobin, Grade 1, Grade 1** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **5** | **2** | **4** | **2** |
| **Hemoglobin, Grade 2, Grade 2** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0** | **1** | **0** | **0** |
| **Neutrophils Decrease, Grade 0, Grade 0** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **32** | **36** | **38** | **33** |
| **Neutrophils Decrease, Grade 0, Grade 1** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **8** | **1** | **8** | **6** |
| **Neutrophils Decrease, Grade 1, Grade 0** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1** | **5** | **2** | **2** |
| **Neutrophils Decrease, Grade 1, Grade 1** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1** | **2** | **1** | **5** |

| | | | | | |
|---|---|---|---|---|---|
| **Neutrophils Decrease, Grade 1, Grade 2** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0** | **0** | **0** | **1** |
| **Neutrophils Decrease, Grade 1, Grade 3** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0** | **1** | **0** | **1** |
| **Neutrophils Decrease, Grade 1, Grade 4** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1** | **0** | **0** | **0** |
| **Neutrophils Decrease, Grade 2, Grade 0** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **2** | **0** | **0** | **1** |
| **Neutrophils Decrease, Grade 2, Grade 1** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1** | **0** | **0** | **0** |
| **Neutrophils Decrease, Grade 3, Grade 0** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **1** | **1** | **0** | **0** |
| **Neutrophils Decrease, Grade 3, Grade 1** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0** | **0** | **1** | **0** |
| **Platelets Decrease, Grade 0, Grade 0** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **49** | **46** | **49** | **49** |
| **Platelets Decrease, Grade 1, Grade 0** | **Number Analyzed** | **49 Participants** | **46 Participants** | **50 Participants** | **49 Participants** |
| | | **0** | **0** | **1** | **0** |

| | | | | | |
|---|---|---|---|---|---|
| WBC Decrease, Grade 0, Grade 0 | Number Analyzed | 49 Participants | 46 Participants | 50 Participants | 49 Participants |
| | | 44 | 43 | 43 | 44 |
| WBC Decrease, Grade 0, Grade 1 | Number Analyzed | 49 Participants | 46 Participants | 50 Participants | 49 Participants |
| | | 4 | 1 | 1 | 2 |
| WBC Decrease, Grade 1, Grade 0 | Number Analyzed | 49 Participants | 46 Participants | 50 Participants | 49 Participants |
| | | 1 | 2 | 3 | 2 |
| WBC Decrease, Grade 1, Grade 1 | Number Analyzed | 49 Participants | 46 Participants | 50 Participants | 49 Participants |
| | | 0 | 0 | 3 | 1 |

**No statistical analysis provided for The number of participants with abnormal hematological, renal, and hepatic panel test results by Grade values at Day 8 versus baseline (Day 1) Grade values**

**15. Secondary Outcome Measure: The number of participants with abnormal hematological, renal, and hepatic panel test results by Grade values at Day 176 versus Day 169 Grade values [ Time Frame: Day 176 compared to pre-Dose 2 at Day 169 ]**

| | |
|---|---|
| Measure Type | Number |
| Measure Name | The number of participants with abnormal hematological, renal, and hepatic panel test results by Grade values at Day 176 versus Day 169 Grade values |
| Measure Description | Panel tests include measures of ALT, AST, creatinine, hemoglobin, neutrophils decrease, platelets decrease and white blood cells (WBC) decrease. Categories reported when comparing Day 169 and laboratory reference range hematological, renal and hepatic laboratory results are defined as follows: <parameter>,<grade at baseline>,<grade at timing>, where Grade 0=within reference range, Grade 1= mild, Grade 2=moderate, Grade 3=severe and Grade 4=potentially life threatening laboratory abnormality. |
| Time Frame | Day 176 compared to pre-Dose 2 at Day 169 |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| **The analysis was performed on the Exposed Set. Only the participants with haematological, renal, and hepatic panel test data available at Day 176 were reported in this outcome measure.** |

**Reporting Groups**

| | **Description** |
|---|---|
| **altSonflex1-2-3 Low Dose** | **Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169.** |
| **altSonflex1-2-3 Medium Dose** | **Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.** |
| **altSonflex1-2-3 High Dose** | **Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.** |
| **Control** | **Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169.** |

**Measured Values**

| | | **altSonflex1-2-3 Low Dose** | **altSonflex1-2-3 Medium Dose** | **altSonflex1-2-3 High Dose** | **Control** |
|---|---|---|---|---|---|
| **Overall Number of Participants Analyzed** | | **46** | **43** | **46** | **49** |
| **Number [units: Participants]** | | | | | |
| **ALT, Grade 0, Grade 0** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **45** | **43** | **45** | **48** |

| | | | | | |
|---|---|---|---|---|---|
| ALT, Grade 0, Grade 1 | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 | 0 | 0 | 1 |
| ALT, Grade 1, Grade 0 | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 | 0 | 0 | 0 |
| ALT, Grade 1, Grade 2 | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 | 0 | 1 | 0 |
| AST, Grade 0, Grade 0 | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 45 | 43 | 45 | 48 |
| AST, Grade 1, Grade 0 | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 | 0 | 0 | 1 |
| AST, Grade 1, Grade 1 | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 | 0 | 1 | 0 |
| Creatinine, Grade 0, Grade 0 | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 45 | 43 | 46 | 48 |
| Creatinine, Grade 0, Grade 2 | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 | 0 | 0 | 1 |
| Hemoglobin, Grade 0, Grade 0 | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 43 | 35 | 39 | 41 |

| | | | | | |
|---|---|---|---|---|---|
| **Hemoglobin, Grade 0, Grade 1** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **0** | **1** | **1** | **1** |
| **Hemoglobin, Grade 1, Grade 0** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **1** | **1** | **2** | **1** |
| **Hemoglobin, Grade 1, Grade 1** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **1** | **3** | **0** | **2** |
| **Hemoglobin, Grade 1, Grade 2** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **0** | **1** | **2** | **3** |
| **Hemoglobin, Grade 2, Grade 1** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **0** | **2** | **2** | **0** |
| **Hemoglobin, Grade 2, Grade 2** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **1** | **0** | **0** | **0** |
| **Hemoglobin, Grade 2, Grade 3** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **0** | **0** | **0** | **1** |
| **Neutrophils Decrease, Grade 0, Grade 0** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **38** | **32** | **41** | **41** |
| **Neutrophils Decrease, Grade 0, Grade 1** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **2** | **6** | **2** | **1** |

| | | | | | |
|---|---|---|---|---|---|
| **Neutrophils Decrease, Grade 1, Grade 0** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **2** | **2** | **0** | **7** |
| **Neutrophils Decrease, Grade 1, Grade 1** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **2** | **0** | **3** | **0** |
| **Neutrophils Decrease, Grade 1, Grade 2** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **0** | **0** | **0** | **0** |
| **Neutrophils Decrease, Grade 1, Grade 3** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **0** | **0** | **0** | **0** |
| **Neutrophils Decrease, Grade 1, Grade 4** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **0** | **0** | **0** | **0** |
| **Neutrophils Decrease, Grade 2, Grade 0** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **2** | **0** | **0** | **0** |
| **Neutrophils Decrease, Grade 2, Grade 1** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **0** | **0** | **0** | **0** |
| **Neutrophils Decrease, Grade 2, Grade 2** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **0** | **1** | **0** | **0** |
| **Neutrophils Decrease, Grade 3, Grade 0** | **Number Analyzed** | **46 Participants** | **43 Participants** | **46 Participants** | **49 Participants** |
| | | **0** | **1** | **0** | **0** |

| | | | | | |
|---|---|---|---|---|---|
| Neutrophils Decrease, Grade 3, Grade 1 | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 | 1 | 0 | 0 |
| Platelets Decrease, Grade 0, Grade 0 | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 45 | 42 | 45 | 49 |
| Platelets Decrease, Grade 1, Grade 0 | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 | 1 | 1 | 0 |
| WBC Decrease, Grade 0, Grade 0 | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 44 | 40 | 42 | 46 |
| WBC Decrease, Grade 0, Grade 1 | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 | 0 | 0 | 0 |
| WBC Decrease, Grade 1, Grade 0 | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 1 | 2 | 4 | 2 |
| WBC Decrease, Grade 1, Grade 1 | Number Analyzed | 46 Participants | 43 Participants | 46 Participants | 49 Participants |
| | | 0 | 1 | 0 | 1 |

**No statistical analysis provided for The number of participants with abnormal hematological, renal, and hepatic panel test results by Grade values at Day 176 versus Day 169 Grade values**

**16. Secondary Outcome Measure: Anti-measles IgG concentrations expressed as GMCs [ Time Frame: At Day 1 (before the first MR-VAC) and at Day 197 (28 days after the second MR-VAC vaccination) ]**

| Measure Type | Geometric Mean |
|---|---|

| | |
|---|---|
| **Measure Name** | **Anti-measles IgG concentrations expressed as GMCs** |
| **Measure Description** | **Anti-measles IgG concentrations were expressed as GMCs in EU/mL.** |
| **Time Frame** | **At Day 1 (before the first MR-VAC) and at Day 197 (28 days after the second MR-VAC vaccination)** |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| **The analysis was performed on the Immunogenicity Set. Only the participants with anti-measles IgG concentrations data available at the specified timepoints were reported in this outcome measure.** |

**Reporting Groups**

| | **Description** |
|---|---|
| **altSonflex1-2-3 Low Dose** | **Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169.** |
| **altSonflex1-2-3 Medium Dose** | **Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.** |
| **altSonflex1-2-3 High Dose** | **Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.** |
| **Control** | **Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169.** |

**Measured Values**

| | **altSonflex1-2-3 Low Dose** | **altSonflex1-2-3 Medium Dose** | **altSonflex1-2-3 High Dose** | **Control** |
|---|---|---|---|---|
| **Overall Number of Participants Analyzed** | **50** | **50** | **50** | **50** |

| Geometric Mean (95% Confidence Interval) [units: EU/mL] | | | | | |
|---|---|---|---|---|---|
| Day 1 | Number Analyzed | 50 Participants | 50 Participants | 50 Participants | 50 Participants |
| | | 25.4 (24.6 to 26.2) | 25.0 (25.0 to 25.0) | 25.5 (24.5 to 26.4) | 25.8 (24.2 to 27.5) |
| Day 197 | Number Analyzed | 44 Participants | 42 Participants | 44 Participants | 45 Participants |
| | | 1005.0 (855.0 to 1181.3) | 835.6 (685.7 to 1018.3) | 923.9 (783.7 to 1089.0) | 954.1 (836.2 to 1088.6) |

No statistical analysis provided for Anti-measles IgG concentrations expressed as GMCs

17. Secondary Outcome Measure: Anti-rubella IgG concentrations expressed as GMCs [ Time Frame: At Day 1 (before the first MR-VAC) and at Day 197 (28 days after the second MR-VAC vaccination) ]

| | |
|---|---|
| Measure Type | Geometric Mean |
| Measure Name | Anti-rubella IgG concentrations expressed as GMCs |
| Measure Description | Anti-rubella IgG concentrations were expressed as GMCs in EU/mL. |
| Time Frame | At Day 1 (before the first MR-VAC) and at Day 197 (28 days after the second MR-VAC vaccination) |

Population Description

| |
|---|
| Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate. |
| The analysis was performed on the Immunogenicity Set. Only the participants with anti-rubella IgG concentrations data available at the specified timepoint were reported in this outcome measure. |

Reporting Groups

| | Description |
|---|---|
| altSonflex1-2-3 Low Dose | Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169. |
| altSonflex1-2-3 Medium Dose | Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| altSonflex1-2-3 High Dose | Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| Control | Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. |

**Measured Values**

| | | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|---|
| Overall Number of Participants Analyzed | | 50 | 50 | 50 | 50 |
| Geometric Mean (95% Confidence Interval) [units: EU/mL] | | | | | |
| Day 1 | Number Analyzed | 50 Participants | 50 Participants | 50 Participants | 50 Participants |
| | | 1.0 (1.0 to 1.1) | 1.1 (1.0 to 1.2) | 1.2 (1.1 to 1.4) | 1.1 (1.0 to 1.2) |
| Day 197 | Number Analyzed | 44 Participants | 42 Participants | 44 Participants | 45 Participants |
| | | 91.1 (84.4 to 98.3) | 78.3 (68.2 to 89.8) | 85.1 (76.9 to 94.2) | 84.4 (77.7 to 91.7) |

**No statistical analysis provided for Anti-rubella IgG concentrations expressed as GMCs**

**18. Secondary Outcome Measure: Number of participants achieving anti-measles IgG concentrations of ≥150 international units per milliliter (IU/mL) and ≥200**

IU/mL [ Time Frame: At Day 197 (28 days after the second MR-VAC vaccination) ]

| | |
|---|---|
| Measure Type | Count of Participants |
| Measure Name | Number of participants achieving anti-measles IgG concentrations of ≥150 international units per milliliter (IU/mL) and ≥200 IU/mL |
| Measure Description | |
| Time Frame | At Day 197 (28 days after the second MR-VAC vaccination) |

Population Description

| |
|---|
| Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate. |
| The analysis was performed on the Immunogenicity Set. Only the participants with anti-measles IgG concentrations data available at Day 197 were reported in this outcome measure. |

Reporting Groups

| | Description |
|---|---|
| altSonflex1-2-3 Low Dose | Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169. |
| altSonflex1-2-3 Medium Dose | Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| altSonflex1-2-3 High Dose | Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| Control | Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. |

Measured Values

| | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| **Overall Number of Participants Analyzed** | | **44** | **42** | **44** | **45** |
| **Count of Participants [units: Participants]** | | | | | |
| **>= 150 IU/L** | **Number Analyzed** | **44 Participants** | **42 Participants** | **44 Participants** | **45 Participants** |
| | | **44 (100%)** | **41 (97.62%)** | **44 (100%)** | **45 (100%)** |
| **>= 200 IU/L** | **Number Analyzed** | **44 Participants** | **42 Participants** | **44 Participants** | **45 Participants** |
| | | **44 (100%)** | **41 (97.62%)** | **44 (100%)** | **45 (100%)** |

**No statistical analysis provided for Number of participants achieving anti-measles IgG concentrations of ≥150 international units per milliliter (IU/mL) and ≥200 IU/mL**

**19. Secondary Outcome Measure: Number of participants achieving anti-rubella IgG concentrations of ≥4 IU/mL and ≥10 IU/mL [ Time Frame: At Day 197 (28 days after the second MR-VAC vaccination) ]**

| | |
|---|---|
| **Measure Type** | **Count of Participants** |
| **Measure Name** | **Number of participants achieving anti-rubella IgG concentrations of ≥4 IU/mL and ≥10 IU/mL** |
| **Measure Description** | |
| **Time Frame** | **At Day 197 (28 days after the second MR-VAC vaccination)** |

**Population Description**

**Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.**

The analysis was performed on the Immunogenicity Set. Only the participants with anti-rubella IgG concentrations data available at Day 197 were reported in this outcome measure.

Reporting Groups

| | Description |
|---|---|
| altSonflex1-2-3 Low Dose | Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169. |
| altSonflex1-2-3 Medium Dose | Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| altSonflex1-2-3 High Dose | Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169. |
| Control | Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169. |

Measured Values

| | | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|---|
| Overall Number of Participants Analyzed | | 44 | 42 | 44 | 45 |
| Count of Participants [units: Participants] | | | | | |
| >= 4 IU/mL | Number Analyzed | 44 Participants | 42 Participants | 44 Participants | 45 Participants |
| | | 44 (100%) | 42 (100%) | 44 (100%) | 45 (100%) |
| >= 10 IU/mL | Number Analyzed | 44 Participants | 42 Participants | 44 Participants | 45 Participants |
| | | 44 (100%) | 41 (97.62%) | 44 (100%) | 45 (100%) |

**No statistical analysis provided for Number of participants achieving anti-rubella IgG concentrations of ≥4 IU/mL and ≥10 IU/mL**

## Adverse Events

| | |
|---|---|
| **Time Frame** | **Solicited AEs: within 7 days after any vaccination. Unsolicited AEs: within 28 days after any vaccination. All-cause mortality and SAEs: From Day 1 until Day 197.** |
| **Adverse Event Reporting Description** | **No text entered.** |
| **Source Vocabulary Name for Table Default** | **MedDRA 28.1** |
| **Collection Approach for Table Default** | **Systematic Assessment** |

**Reporting Groups**

| | **Description** |
|---|---|
| **altSonflex1-2-3 Low Dose** | **Participants received 2 low doses of altSonflex1-2-3 and 2 doses of the measles and rubella vaccine (MR-VAC) one each on Day 1 and Day 169.** |
| **altSonflex1-2-3 Medium Dose** | **Participants received 2 medium doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.** |
| **altSonflex1-2-3 High Dose** | **Participants received 2 high doses of altSonflex1-2-3 and 2 doses of MR-VAC one each on Day 1 and Day 169.** |
| **Control** | **Participants received 1 dose of the TYPHIBEV vaccine on Day 1 and 1 dose of the Infanrix Hexa vaccine on Day 169, along with 2 doses of MR-VAC on Day 1 and Day 169.** |

### All-Cause Mortality

| | **altSonflex1-2-3 Low Dose** | **altSonflex1-2-3 Medium Dose** | **altSonflex1-2-3 High Dose** | **Control** |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| **Total** | | | | |
| **# participants affected / at risk** | **0/50 (0.00%)** | **0/50 (0.00%)** | **0/50 (0.00%)** | **0/50 (0.00%)** |

## Serious Adverse Events

**Serious Adverse Events**

| | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|
| **Total, serious adverse events** | | | | |
| **# participants affected / at risk** | **1/50 (2.00%)** | **0/50 (0.00%)** | **0/50 (0.00%)** | **0/50 (0.00%)** |
| **Infections and infestations** | | | | |
| **Gastroenteritis[1, †]** | | | | |
| **# participants affected / at risk** | **1/50 (2.00%) [50]** | **0/50 (0.00%) [50]** | **0/50 (0.00%) [50]** | **0/50 (0.00%) [50]** |
| **# events** | **1** | **0** | **0** | **0** |

| | |
|---|---|
| **†** | **Events were collected by systematic assessment** |
| **1** | **Term from vocabulary, MedDRA 28.1** |

## Other Adverse Events

**Frequency Threshold**

| | |
|---|---|
| **Threshold above which other adverse events are reported** | **0%** |

**Other Adverse Events**

| | altSonflex1-2-3 Low Dose | altSonflex1-2-3 Medium Dose | altSonflex1-2-3 High Dose | Control |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| **Total, other (not including serious) adverse events** | | | | |
| **# participants affected / at risk** | **41/50 (82.00%)** | **35/50 (70.00%)** | **42/50 (84.00%)** | **40/50 (80.00%)** |
| **General disorders and administration site conditions** | | | | |
| **Administration site pain[1, †]** | | | | |
| **# participants affected / at risk** | **15/50 (30.00%) [50]** | **19/50 (38.00%) [50]** | **23/50 (46.00%) [50]** | **15/50 (30.00%) [50]** |
| **# events** | **22** | **27** | **28** | **16** |
| **General disorders and administration site conditions** | | | | |
| **Administration site swelling[1, †]** | | | | |
| **# participants affected / at risk** | **12/50 (24.00%) [50]** | **13/50 (26.00%) [50]** | **18/50 (36.00%) [50]** | **8/50 (16.00%) [50]** |
| **# events** | **14** | **19** | **19** | **8** |
| **General disorders and administration site conditions** | | | | |
| **Pyrexia[1, †]** | | | | |
| **# participants affected / at risk** | **12/50 (24.00%) [50]** | **12/50 (24.00%) [50]** | **9/50 (18.00%) [50]** | **10/50 (20.00%) [50]** |
| **# events** | **14** | **16** | **14** | **13** |

| | | | | |
|---|---|---|---|---|
| **General disorders and administration site conditions** | | | | |
| **Administration site erythema[1, †]** | | | | |
| **# participants affected / at risk** | **8/50 (16.00%) [50]** | **7/50 (14.00%) [50]** | **10/50 (20.00%) [50]** | **7/50 (14.00%) [50]** |
| **# events** | **10** | **9** | **13** | **7** |
| **General disorders and administration site conditions** | | | | |
| **Feeling hot[1, †]** | | | | |
| **# participants affected / at risk** | **1/50 (2.00%) [50]** | **0/50 (0.00%) [50]** | **1/50 (2.00%) [50]** | **0/50 (0.00%) [50]** |
| **# events** | **1** | **0** | **1** | **0** |
| **Infections and infestations** | | | | |
| **Upper respiratory tract infection[1, †]** | | | | |
| **# participants affected / at risk** | **8/50 (16.00%) [50]** | **8/50 (16.00%) [50]** | **6/50 (12.00%) [50]** | **13/50 (26.00%) [50]** |
| **# events** | **10** | **8** | **6** | **13** |
| **Infections and infestations** | | | | |
| **Rhinitis[1, †]** | | | | |
| **# participants affected / at risk** | **5/50 (10.00%) [50]** | **8/50 (16.00%) [50]** | **8/50 (16.00%) [50]** | **12/50 (24.00%) [50]** |
| **# events** | **5** | **8** | **8** | **13** |

| | | | | |
|---|---|---|---|---|
| **Infections and infestations** | | | | |
| **Gastroenteritis[1,†]** | | | | |
| **# participants affected / at risk** | **4/50 (8.00%) [50]** | **5/50 (10.00%) [50]** | **2/50 (4.00%) [50]** | **6/50 (12.00%) [50]** |
| **# events** | **4** | **5** | **2** | **6** |
| **Infections and infestations** | | | | |
| **Tonsillitis[1,†]** | | | | |
| **# participants affected / at risk** | **5/50 (10.00%) [50]** | **1/50 (2.00%) [50]** | **4/50 (8.00%) [50]** | **1/50 (2.00%) [50]** |
| **# events** | **5** | **1** | **4** | **1** |
| **Infections and infestations** | | | | |
| **Amoebiasis[1,†]** | | | | |
| **# participants affected / at risk** | **0/50 (0.00%) [50]** | **4/50 (8.00%) [50]** | **3/50 (6.00%) [50]** | **0/50 (0.00%) [50]** |
| **# events** | **0** | **4** | **3** | **0** |
| **Infections and infestations** | | | | |
| **Nasopharyngitis[1,†]** | | | | |
| **# participants affected / at risk** | **2/50 (4.00%) [50]** | **1/50 (2.00%) [50]** | **0/50 (0.00%) [50]** | **1/50 (2.00%) [50]** |
| **# events** | **2** | **1** | **0** | **1** |
| **Infections and infestations** | | | | |
| **Otitis media[1,†]** | | | | |

| | | | | |
|---|---|---|---|---|
| # participants affected / at risk | 0/50 (0.00%) [50] | 2/50 (4.00%) [50] | 1/50 (2.00%) [50] | 1/50 (2.00%) [50] |
| # events | 0 | 2 | 1 | 1 |
| Infections and infestations | | | | |
| Oral candidiasis[1,†] | | | | |
| # participants affected / at risk | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] | 2/50 (4.00%) [50] |
| # events | 1 | 0 | 0 | 2 |
| Infections and infestations | | | | |
| Pharyngitis[1,†] | | | | |
| # participants affected / at risk | 0/50 (0.00%) [50] | 2/50 (4.00%) [50] | 0/50 (0.00%) [50] | 1/50 (2.00%) [50] |
| # events | 0 | 2 | 0 | 1 |
| Infections and infestations | | | | |
| Pulmonary tuberculosis[1,†] | | | | |
| # participants affected / at risk | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] | 3/50 (6.00%) [50] | 0/50 (0.00%) [50] |
| # events | 0 | 0 | 3 | 0 |
| Infections and infestations | | | | |
| Conjunctivitis[1,†] | | | | |
| # participants affected / at risk | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] |

| | | | | |
|---|---|---|---|---|
| # events | 1 | 0 | 0 | 0 |
| Infections and infestations | | | | |
| Escherichia infection[1, †] | | | | |
| # participants affected / at risk | 0/50 (0.00%) [50] | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] |
| # events | 0 | 1 | 0 | 0 |
| Infections and infestations | | | | |
| Foot and mouth disease[1, †] | | | | |
| # participants affected / at risk | 0/50 (0.00%) [50] | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] |
| # events | 0 | 1 | 0 | 0 |
| Infections and infestations | | | | |
| Malaria[1, †] | | | | |
| # participants affected / at risk | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] |
| # events | 1 | 0 | 0 | 0 |
| Infections and infestations | | | | |
| Norovirus infection[1, †] | | | | |
| # participants affected / at risk | 0/50 (0.00%) [50] | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] |
| # events | 0 | 1 | 0 | 0 |

| | | | | |
|---|---|---|---|---|
| **Infections and infestations** | | | | |
| **Otitis media acute[1,†]** | | | | |
| **# participants affected / at risk** | **0/50 (0.00%) [50]** | **0/50 (0.00%) [50]** | **0/50 (0.00%) [50]** | **1/50 (2.00%) [50]** |
| **# events** | **0** | **0** | **0** | **1** |
| **Infections and infestations** | | | | |
| **Rotavirus infection[1,†]** | | | | |
| **# participants affected / at risk** | **0/50 (0.00%) [50]** | **1/50 (2.00%) [50]** | **0/50 (0.00%) [50]** | **0/50 (0.00%) [50]** |
| **# events** | **0** | **1** | **0** | **0** |
| **Infections and infestations** | | | | |
| **Scabies[1,†]** | | | | |
| **# participants affected / at risk** | **0/50 (0.00%) [50]** | **0/50 (0.00%) [50]** | **1/50 (2.00%) [50]** | **0/50 (0.00%) [50]** |
| **# events** | **0** | **0** | **1** | **0** |
| **Gastrointestinal disorders** | | | | |
| **Diarrhoea[1,†]** | | | | |
| **# participants affected / at risk** | **3/50 (6.00%) [50]** | **4/50 (8.00%) [50]** | **3/50 (6.00%) [50]** | **3/50 (6.00%) [50]** |
| **# events** | **3** | **4** | **3** | **3** |
| **Gastrointestinal disorders** | | | | |
| **Vomiting[1,†]** | | | | |

| | | | | |
|---|---|---|---|---|
| # participants affected / at risk | 2/50 (4.00%) [50] | 0/50 (0.00%) [50] | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] |
| # events | 2 | 0 | 1 | 0 |
| Gastrointestinal disorders | | | | |
| Constipation[1, †] | | | | |
| # participants affected / at risk | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] |
| # events | 0 | 0 | 1 | 0 |
| Gastrointestinal disorders | | | | |
| Teething[1, †] | | | | |
| # participants affected / at risk | 0/50 (0.00%) [50] | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] |
| # events | 0 | 1 | 0 | 0 |
| Investigations | | | | |
| Haemoglobin decreased[1, †] | | | | |
| # participants affected / at risk | 1/50 (2.00%) [50] | 1/50 (2.00%) [50] | 2/50 (4.00%) [50] | 4/50 (8.00%) [50] |
| # events | 1 | 1 | 2 | 4 |
| Investigations | | | | |
| White blood cell count decreased[1, †] | | | | |
| # participants affected / at risk | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] |
| # events | 1 | 0 | 1 | 0 |

| | | | | |
|---|---|---|---|---|
| **Investigations** | | | | |
| **Alanine aminotransferase increased[1, †]** | | | | |
| **# participants affected / at risk** | **0/50 (0.00%) [50]** | **0/50 (0.00%) [50]** | **1/50 (2.00%) [50]** | **0/50 (0.00%) [50]** |
| **# events** | **0** | **0** | **1** | **0** |
| **Investigations** | | | | |
| **Platelet count increased[1, †]** | | | | |
| **# participants affected / at risk** | **0/50 (0.00%) [50]** | **0/50 (0.00%) [50]** | **1/50 (2.00%) [50]** | **0/50 (0.00%) [50]** |
| **# events** | **0** | **0** | **1** | **0** |
| **Skin and subcutaneous tissue disorders** | | | | |
| **Dermatitis allergic[1, †]** | | | | |
| **# participants affected / at risk** | **0/50 (0.00%) [50]** | **0/50 (0.00%) [50]** | **1/50 (2.00%) [50]** | **2/50 (4.00%) [50]** |
| **# events** | **0** | **0** | **1** | **2** |
| **Skin and subcutaneous tissue disorders** | | | | |
| **Rash[1, †]** | | | | |
| **# participants affected / at risk** | **1/50 (2.00%) [50]** | **1/50 (2.00%) [50]** | **0/50 (0.00%) [50]** | **1/50 (2.00%) [50]** |
| **# events** | **1** | **1** | **0** | **1** |
| **Skin and subcutaneous tissue disorders** | | | | |

| | | | | |
|---|---|---|---|---|
| Dermatitis[1,†] | | | | |
| # participants affected / at risk | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] |
| # events | 1 | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | | |
| Dermatitis atopic[1,†] | | | | |
| # participants affected / at risk | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] | 1/50 (2.00%) [50] |
| # events | 0 | 0 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | | |
| Pruritus[1,†] | | | | |
| # participants affected / at risk | 0/50 (0.00%) [50] | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] |
| # events | 0 | 1 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | | |
| Urticaria[1,†] | | | | |
| # participants affected / at risk | 0/50 (0.00%) [50] | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] |
| # events | 0 | 1 | 0 | 0 |
| Blood and lymphatic system disorders | | | | |
| Neutropenia[1,†] | | | | |
| # participants affected / at risk | 3/50 (6.00%) [50] | 1/50 (2.00%) [50] | 1/50 (2.00%) [50] | 2/50 (4.00%) [50] |

| | | | | |
|---|---|---|---|---|
| # events | 3 | 1 | 1 | 2 |
| Respiratory, thoracic and mediastinal disorders | | | | |
| Cough[1, †] | | | | |
| # participants affected / at risk | 0/50 (0.00%) [50] | 2/50 (4.00%) [50] | 2/50 (4.00%) [50] | 0/50 (0.00%) [50] |
| # events | 0 | 2 | 2 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | | |
| Rhinitis allergic[1, †] | | | | |
| # participants affected / at risk | 0/50 (0.00%) [50] | 2/50 (4.00%) [50] | 0/50 (0.00%) [50] | 1/50 (2.00%) [50] |
| # events | 0 | 3 | 0 | 1 |
| Eye disorders | | | | |
| Conjunctivitis allergic[1, †] | | | | |
| # participants affected / at risk | 0/50 (0.00%) [50] | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] |
| # events | 0 | 1 | 0 | 0 |
| Eye disorders | | | | |
| Eye discharge[1, †] | | | | |
| # participants affected / at risk | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] |
| # events | 1 | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | | |

| | | | | |
|---|---|---|---|---|
| Dehydration[1, †] | | | | |
| # participants affected / at risk | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] | 2/50 (4.00%) [50] |
| # events | 0 | 0 | 0 | 2 |
| Psychiatric disorders | | | | |
| Irritability[1, †] | | | | |
| # participants affected / at risk | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] |
| # events | 1 | 0 | 1 | 0 |
| Injury, poisoning and procedural complications | | | | |
| Thermal burn[1, †] | | | | |
| # participants affected / at risk | 0/50 (0.00%) [50] | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] |
| # events | 0 | 1 | 0 | 0 |
| Nervous system disorders | | | | |
| Fontanelle bulging[1, †] | | | | |
| # participants affected / at risk | 1/50 (2.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] | 0/50 (0.00%) [50] |
| # events | 1 | 0 | 0 | 0 |

| | |
|---|---|
| † | Events were collected by systematic assessment |
| 1 | Term from vocabulary, MedDRA |
| 2 | Term from vocabulary, MedDRA 28.1 |