

## **Latest result summary**

### **Outcome measures**

The primary outcome measure was abnormal FHR defined as normal (110 to 160 beats/min (bpm) throughout labor and delivery) or abnormal (absent, <110 or >160 beats/min). The measurement of FHR continued till the woman delivered at an interval of every 30 minutes in the first stage of labor and every 15 minutes during the second stage of labor. The start of FHR auscultation within the first 10 minutes following the uterine quiescence. The report or documentation for the control arm was on the prepared follow-up sheet, where the count would be rounded to the nearest 5 beats per minute increment. Abnormal FHR reached after at least one confirmed measurement at any point during labor.

Secondary outcomes included the Apgar score at first and fifth minutes (abnormal is defined as an Apgar score <7); Birth outcomes (i.e., normal, admission to the neonatal unit, FSB), Neonatal outcome at 24-h (i.e., normal, very early neonatal death, still admitted to the neonatal unit) [1]. Obstetric time intervals included: admission to abnormal FHR detection, admission to delivery, from abnormal FHR detection to delivery.

**Baseline fetal heart rate:** it is the mean level of the FHR determined over 5-10 minutes ranging from 110 to 160bpm, excluding accelerations and decelerations[2]. If the baseline FHR is <110 beats/min, it is termed bradycardia; if the baseline FHR is >160 beats/min, it was termed tachycardia [3].

**Fresh stillbirth/intrapartum death:** infants born dead after 37 weeks of gestation without signs of skin dis-integration or maceration; the death is assumed to have occurred less than 12 hours before delivery; excludes those born with severe, lethal congenital abnormalities[4, 5].

**Very early neonatal death:** The death must have occurred within 24 hours of delivery[4, 5].

**Apgar score:** The Apgar score, a tool used to assess well-being at 1<sup>st</sup> and 5<sup>th</sup> minutes after birth, incorporates five elements: respiratory effort, heart rate, reflex irritability, muscle tone, and color. A total score of 7 to 10 is normal, a score of less than 7 indicates impairment and indicates the need for an immediate resuscitation[6].

**Adverse birth outcomes:** include FSB, and newborns admitted to the neonatal unit immediately after the childbirth.

**Adverse neonatal outcomes:** Include early neonatal deaths within the first 24 hours of life and newborns still admitted to the neonatal unit within 24 hours of life.

**Obstetrics time interval:** The time from admission of laboring mother to fetal delivery. This was divided in three: Admission to Abnormal fetal heart rate, abnormal fetal heart rate to delivery, and admission to fetal delivery.

### Baseline characteristics of study participants

A total of 2518 women were enrolled in the study, with 1259 assigned to Moyo and 1259 assigned to Pinard fetoscope (Figure 2). The mean age of the women was  $25.4 \pm 4.76$  with majority of the women were in the age range of 20 to 35 years, 1125 (89.4%) in Moyo arm versus 1134 (90.1%) in Pinard arm. Furthermore, 429(50%) of women were multiparous followed by 484(38.5%) of women who were primiparous in both arms. In a total of 1259 women enrolled in Moyo arm, 523(41.7%) had attended the fourth ANC while 526(41.9%) had completed the fourth visit antenatal care in Pinard arm. When compared to Pinard fetoscope, women referred from health facilities other than study sites were higher in the Moyo arm.

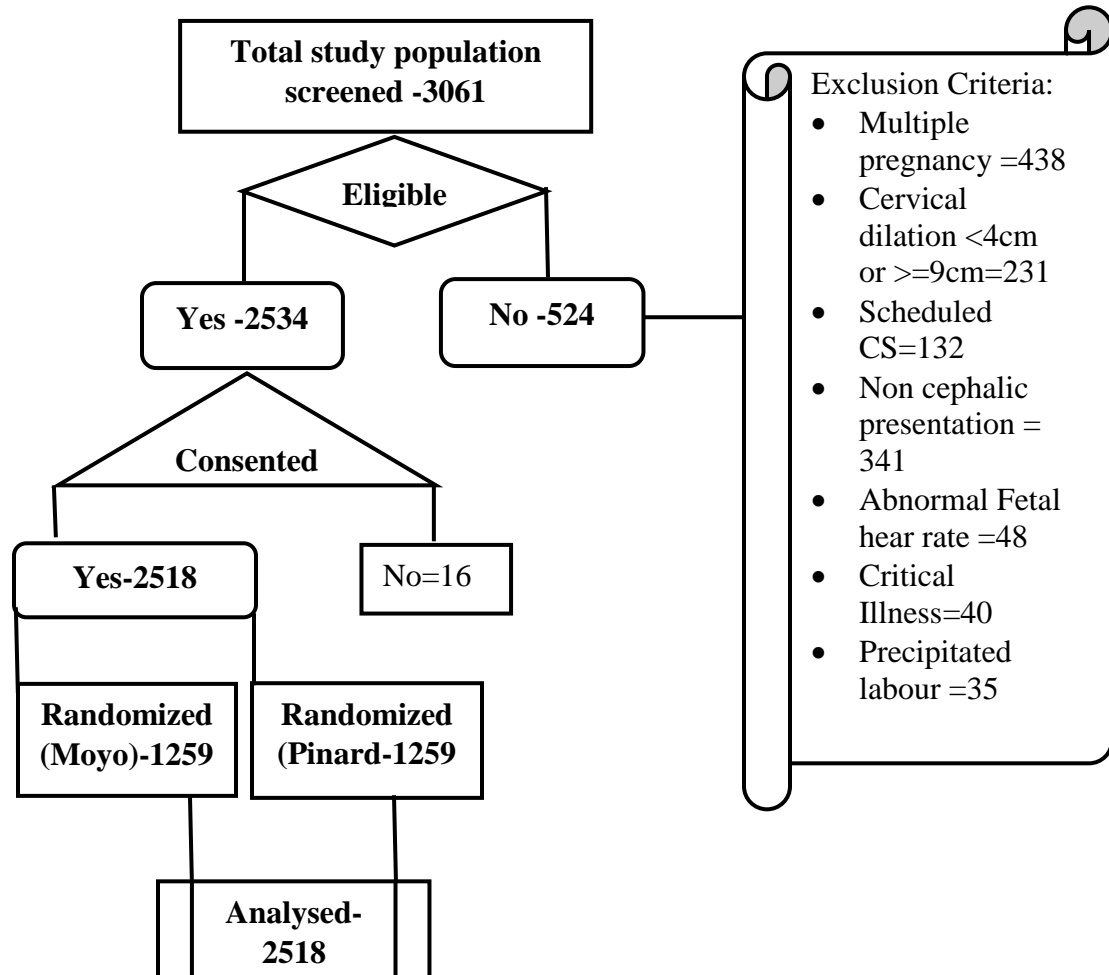


Figure 1: Flow chart of the study population for an effectiveness study conducted in General Hospitals of Southern Ethiopia, 2022/23.

**Key outcomes:** In the Moyo and Pinard fetoscope arms, abnormal fetal heart rate was found in 60 (5.1%) vs 30 (2.4%) ( $p = 0.001$ ), respectively. A shorter time interval from the detection of abnormal fetal heart rate to delivery was found in the Moyo arm, with a mean (SD) of 42.5 (8.4) minutes compared with 53.7 (11.1) minutes in the Pinard fetoscope arm ( $p = 0.001$ ). Moreover, the Moyo arm had shorter time intervals from admission to delivery compared with Pinard fetoscope arms, with a median (IQR) of 220 (165,470) minutes vs 240 (180,575) minutes ( $p = 0.001$ ), respectively. However, no significant difference was observed for the time interval from admission to abnormal fetal heart rate detection ( $p=0.21$ ), poor delivery outcome ( $p = 0.762$ ), a first-minute APGAR score  $<7/10$  ( $p = 0.23$ ), a fifth-minute APGAR score  $<7/10$  ( $p = 0.13$ ), and adverse neonatal outcomes within 24 hours of birth ( $p = 0.16$ ) in both arms.

**Adverse event:** No adverse event was detected related to the device

**Reference:**

1. Lie KK, Grøholt E-K, Eskild A: **Association of cerebral palsy with Apgar score in low and normal birthweight infants: population based cohort study.** *Bmj* 2010, **341**.
2. Pediatrics AAo: **American College of Obstetricians and Gynecologists Fetal heart rate monitoring.** *Guidelines for perinatal care 7th ed* Washington, DC: American College of Obstetricians and Gynecologists 2012.
3. Parer J, Quilligan E, Boehm F, Depp R, Devoe LD, Divon M, Greene K, Harvey C, Hauth J, Huddleston J: **Electronic fetal heart rate monitoring: research guidelines for interpretation.** *American journal of obstetrics and gynecology* 1997, **177**(6):1385-1390.
4. Pellegrin S, Munoz FM, Padula M, Heath PT, Meller L, Top K, Wilmshurst J, Wiznitzer M, Das MK, Hahn CD: **Neonatal seizures: Case definition & guidelines for data collection, analysis, and presentation of immunization safety data.** *Vaccine* 2019, **37**(52):7596.
5. Organization WH: **Monitoring emergency obstetric care: a handbook:** World Health Organization; 2009.
6. Rosen TS, Bateman D: **The Effects of Gender in Neonatal Medicine.** In: *Principles of Gender-Specific Medicine.* edn.: Elsevier; 2010: 3-17.