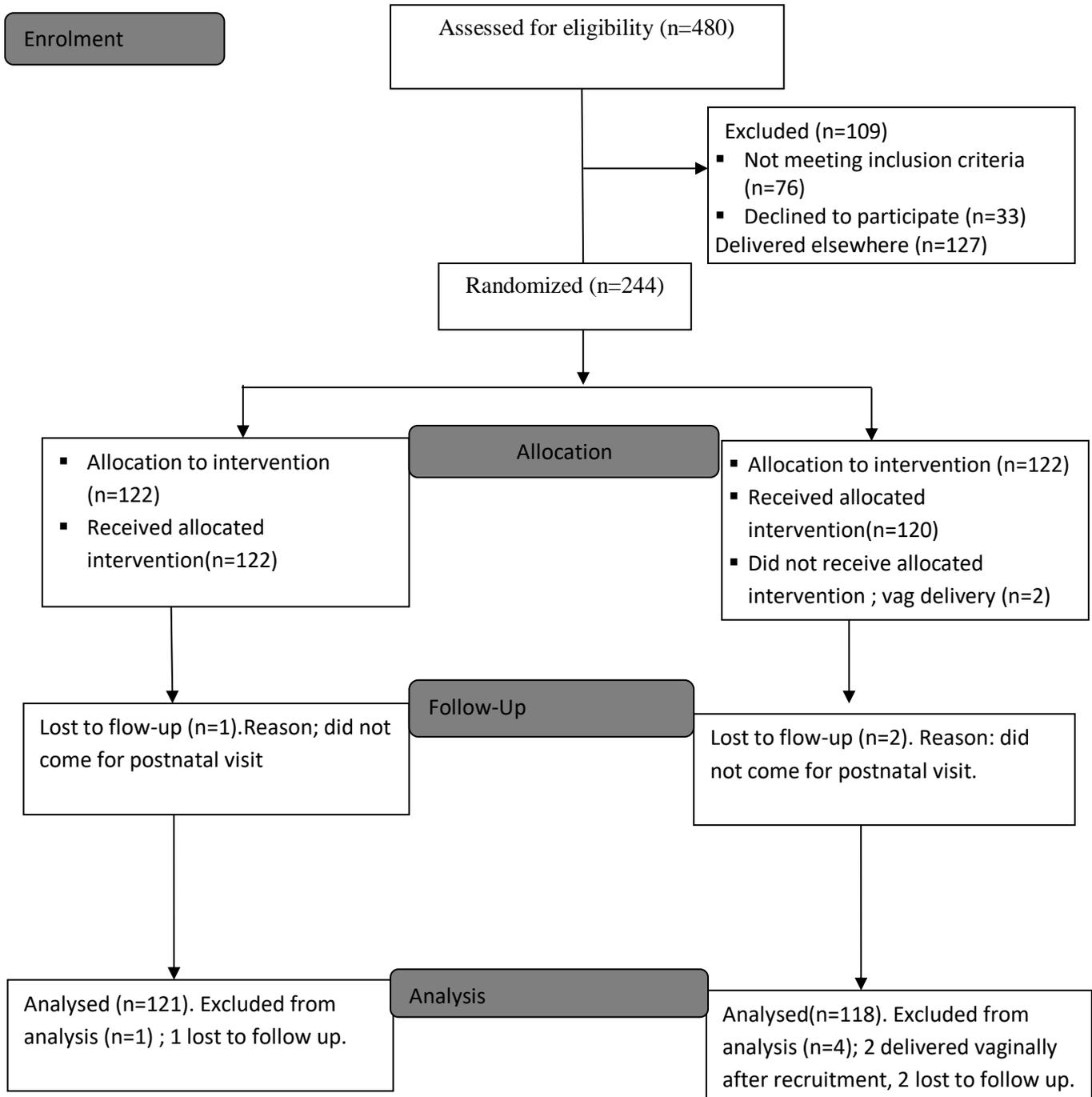


RESULTS

FIGURE 1. CONSORT FLOW DIAGRAM



TableI: Socio-demographic, Obstetrics characteristics, side effect and duration of hospital stay.

Variables	Preoperative(121)	Postoperative(118)	P-value	RR(95% CI)
Mean age	29.4±5.4	30.4±5.0	0.23	
Marital status:				
Single	5(2.1)	10(4.2)		
Married	116(48.5)	108(45.2)	0.26	0.64 (0.31-1.33)
Parity:				
Primigravida	42(17.6)	35(4.6)		
Multipara	62(25.9)	68(28.5)	0.37	0.94 (0.76-1.00)
Grandmultipara	17(7.1)	15(6.3)		
Gestational age(weeks):				
Preterm	9(3.8)	5(2.1)		
Term	100(41.8)	98(41.0)	0.11	0.57 (0.44-1.35)
Post term	12(5.0)	15(6.3)		
Booking status:				
Booked	72(30.1)	70(29.3)		
Unbooked	49(20.5)	48(20.1)	0.97	1.0 (0.78-1.30)
Social class:				
1	16(6.7)	21(8.8)		
2	21(8.8)	30(12.6)		
3	20(8.4)	15(6.3)	0.84	1.0 (0.99-1.75)
4	30(12.6)	26(10.9)		
5	30(12.6)	26(10.9)		
No of vaginal examinations:				

None	42(17.6)	54(22.6)		
1-5	27(11.3)	15(6.3)	0.07	1.71 (0.79-2.31)
>5	52(21.8)	49(20.4)		
Membrane status				
Intact	58(24.3)	60(25.1)		
Ruptured	63(26.4)	58(24.3)	0.35	0.94 (0.73-1.21)
Duration of membrane rupture:				
≤12hours	20(8.4)	16(6.7)		
>12hours	43(18.0)	42(17.6)	0.76	1.1 (0.77-1.57)
Obstructed labour:				
Yes	18(7.5)	12(5.0)		
No	103(43.1)	102(44.4)	0.36	1.19 (0.87-1.65)
Type of caesarean section:				
Elective	41(17.2)	36(15.1)		
Emergency	80(33.5)	82(34.3)	0.97	1.08 (0.83-1.40)
Duration of hospital stay:				
≤7	97(40.6)	95(39.7)		
8-14	18(7.5)	15(6.3)	0.3	0.74 (0.15-1.0)
>14	6(2.5)	8(3.3)		

Table I shows the socio-demographic, Obstetrics characteristics, side effect and duration of hospital stay among the study participants between the preoperative and postoperative vaginal

cleansing groups. The baseline maternal characteristics were similar in both preoperative and postoperative vaginal cleansing groups. The mean age of the preoperative vaginal cleansing group was 29.4 ± 5.4 and that of postoperative vaginal cleansing group was 30.4 ± 5.0 . There was no statistically significant difference among the two groups in age, marital status, parity, gestational age, booking status, social class, and number of vaginal examinations, membrane status, and duration of membrane rupture, type of caesarean section and duration of hospital stay. No participant reacted to Povidone iodine. All had the P-values that were >0.05 . However, overall assessment revealed that the majority of the women were multiparous 130(54.4%), booked (142) 59.4%, and with their pregnancies at term 198(82.8%) during the period of recruitment. Furthermore, majority of the women were in the lower ladder of socioeconomic class (class 4 and 5). One hundred and eighteen (49.4%) had intact fetal membranes while 121 (50.6%) of the women had rupture of fetal membranes prior to the caesarean section while 85(35.6%) had duration of membrane rupture beyond 12hours. Thirty (12.5%) of the women had a diagnosis of obstructed labour prior to the surgery. Most of the surgeries were emergency caesarean section 162 (67.8%) and the majority 192 (80.3%) of the women who had surgery were discharged within 7 days.

Table II: Comparison of medical disorders of pregnancy among the two groups.

Variables	Preoperative(121)	Postoperative(118)	P-value	RR(CI)
OBESITY				
Yes	2(1.7)	1(0.8)	0.51	1.32(0.59-2.9)
No	119(98.3)	117(99.2)		
DIABETES				
Yes	1(0.8)	1(0.8)	0.74	0.99(0.25-3.9)
No	120(99.2)	117(99.2)		
ANAEMIA				
Yes	5(4.1)	5(4.2)	0.97	0.99(0.52-1.86)
No	116(95.9)	113(95.8)		
HYPERTENSION				
Yes	9(7.4)	12(10.2)	0.78	0.88(0.53-1.47)
No	106(89.8)	112(92.6)		

Table II showed comparison of the medical disorders of pregnancy between the preoperative and postoperative vaginal Povidone iodine group. There was no statistically significant difference between the 2 groups

Table III: Summary of frequency distribution of the outcomes among the study groups

Outcome variables	Group 1 121(50.6%)	Group 2 118(49.6%)	Total 239(100%)	P-value	RR(CI)
Total infectious morbidity	4(1.7%)	30(12.6%)	34(14.3%).	0.00005	0.13 (0.05-0.36)
Endometritis	2(0.8%)	11(4.6%)	13(5.4%).	0.009	0.18 (0.04-0.78)
Wound infection	2(0.8%)	9(3.8%)	11(4.6%).	0.032	0.22 (0.05-0.98)
Pyrexia	0(0%)	10(4.2%)	10(4.2%).	0.0007	0.01 (0.007-0.16)

Table IV shows the summary of the distribution of outcomes. Of the 244 participants randomised, 5 participants were excluded from the analysis based on the study protocol(2 participants in the postoperative vaginal cleansing group delivered vaginally in the theatre, 2 participants were lost to follow up in the postoperative vaginal cleansing group while 1 person in the preoperative vaginal group was lost to follow up. These 3 participants did not come for postnatal visit). Of the 239 were analysed there were 121(50.6%) patients in the preoperative vaginal cleansing group and 118(49.4%) patients in the immediate postoperative vaginal cleansing group. There were 34/239(14.3%) total cases of post caesarean maternal infectious morbidity among the study population; 4/121(1.7%) in the preoperative Povidone iodine vaginal cleansing group and 30/118(12.6%) in the immediate postoperative vaginal cleansing group, P-value 0.00005, RR 0.13, CI-0.05-0.36).This was statistically significant. There were 13/239(5.4%), 11/239(4.6%) and

10/239(4.2%) cases of post caesarean endometritis, wound infection and pyrexia respectively. The infectious morbidities were more in the postoperative vaginal Povidone iodine cleansing group than the preoperative vaginal cleansing group (4.6%, 3.8%, 4.2% compare to 0.8%, 0.8% and 0%) for endometritis, wound infection and pyrexia respectively.

Table IV. Comparison of incidence of Post-caesarean maternal infectious morbidity among women stratified by intact or ruptured membranes.

Variables	Preoperative	Postoperative	P-value	Relative Risk/CI
Intact membranes	N=58	N=60		
Total infections	0(0%)	1(1.7%)	0.51	1.01
Endometritis	0(0%)	0(0%)	1	1
Wound infection	0(0%)	1(1.7%)	0.51	1.01
Pyrexia	0(0%)	0(0%)	1	1
Ruptured membranes				
Total infection	4(6.4%)	17(29.3%)	0.001	0.22(0.08-0.61)
Endometritis	2(3.2%)	8(13.8%)	0.04	0.23(0.05-1.03)
Wound infection				

Pyrexia	2(3.2%)	5(8.6%)	0.26	0.37(0.07-1.82)
	0(0%)	4(6.9%)	0.04	0.40(0.08-2.08)

The incidence of post caesarean maternal infectious morbidities among the study participants stratified by whether the membrane was intact or ruptured are shown in table IV. The subgroup analysis shows that among women with intact fetal membranes, there was no statistically significant difference in post caesarean maternal infection (sum total of endometritis, wound infection and pyrexia) between the preoperative and postoperative vaginal cleansing group [0% vs 1.7%, P-value=0.51]. Similarly, there was no statistically significant difference between the two groups for development of endometritis (0% vs 0%), P-value=1, wound infection (0% vs 1.7%), P-value= 0.51, and pyrexia (0% vs 0%, P-value=1).

However, among women with ruptured fetal membranes, composite post caesarean maternal infection (sum total of endometritis, wound infection and pyrexia) showed statistically significant difference between preoperative vaginal cleansing group and postoperative vaginal cleansing group 4(6.4%) vs 17(29.3%) respectively with P-value=0.001; RR 0.22, CI-0.08-0.61). Post

caesarean endometritis occurred in 2(3.2) and 8(13.8%) of women in preoperative and postoperative vaginal cleansing group respectively. This was however not statistically significant (3.2% vs 13.8%), P-value= 0.04; RR 0.23, CI-0.05-1.02). Similarly, postoperative pyrexia and wound infection did not show statistically significant difference among the two groups 0(0%) vs (4)6.9%, P-value=0.04, RR 0.40, CI-0.08-2.08) and (3.2% vs 8.6%), P-value=0.26, RR 0.37, CI-0.07-1.82) respectively.

Table V: Comparison of the incidence of post-caesarean infectious morbidity among women stratified by elective or emergency caesarean section.

Variables	Preoperative	Postoperative	P-value	Relative Risk/CI
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Elective	N=41	N=36		
Total infections	0(0%)	0(0%)	1	1
Endometritis	0(0%)	0(0%)	1	1
Wound infection	0(0%)	0(0%)	1	1
Pyrexia	0(0%)	0(0%)	1	1
Emergency	N=85	N=82		
Total infection	4(5%)	30(36.6%)	0.0001	0.14(0.05-0.37)
Endometritis	2(2.5%)	11(13.4%)	0.02	0.19(0.04-0.81)
Wound infection	2(2.5%)	9(11%)	0.03	0.23(0.05-1.02)
Pyrexia	0(0%)	10(12.2%)	0.002	0.12(0.06-0.52)

Table V is a subgroup analysis of women who had elective caesarean delivery or emergency caesarean delivery. Among women who had elective caesarean section, there was no post caesarean maternal infectious morbidity recorded in either preoperative or postoperative vaginal cleansing group. However, in subgroup analysis of women who had emergency caesarean delivery, the total post caesarean maternal infectious morbidity rate respectively in the two arms was 5% vs 36.6%: P-value=0.0001, RR 0.14, CI-0.05-0.37) and this showed statistically significant difference between the two arms. Furthermore, there was statistically significant difference in the rate of post caesarean endometritis and pyrexia between preoperative and postoperative vaginal cleansing groups {2.5% vs 13.4%: P-value=0.02; RR 0.19, CI-0.04-0.81) and {0% vs 12.2%; p-value 0.002, RR 0.12, CI-0.06-0.52)} respectively. However, wound infection rate did not show statistically significant difference between the two groups {2.5% vs 11%, P-value= 0.03, RR 0.23,CI 0.51-1.02}).