Basic Results

Efficacy of Mifepristone followed by misoprostol compared to misoprostol alone in First trimester miscarriage Treatment - a double-blind randomized controlled trial (MiFirsT)

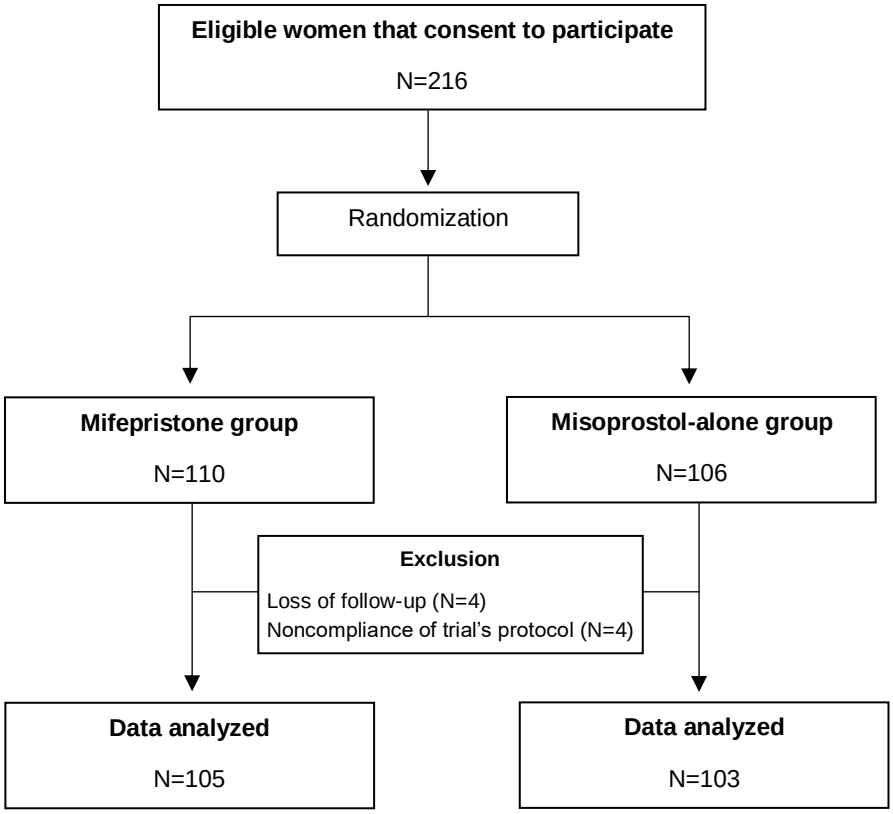

Table 1 – Population demographics and clinical characteristics at randomization.		
Characteristic	**Mifepristone Group (N=105)**	**Misoprostol-Alone Group (N=103)**
Age – years (mean ± SD)	34 ± 5.3	34 ± 5.2
Parity [N (%)]		
0	53 (50.5)	52 (50.5)
≥ 1	52 (49.5)	51 (49.5)
Previous miscarriage [N (%)]		
0	81 (77.1)	87 (84.5)
1	20 (19.0)	12 (11.7)
≥ 2	4 (3.8)	4 (3.9)
Diagnosis [N (%)]		
Anembryonic gestation	18 (17.1)	22 (21.4)
Embryonic death	87 (82.9)	81 (78.6)
Gestational age by CRL*		
5-6 weeks	28 (33.7)	34 (42.5)
7 weeks	28 (33.7)	17 (21.3)
8-9 weeks	27 (32.5)	29 (36.3)
Vaginal bleeding	39 (37.1)	32 (31.1)
Abdominal pain	20 (19.0)	15 (14.6)

CRL – Crown-rump length; * 4 and 1 missing values in mifepristone group and misoprostol-alone group, respectively.

Table 2 – Characteristics of the complete medical treatment and follow-up.		
Characteristic	**Mifepristone Group (N=105)**	**Misoprostol-Alone Group (N=103)**
Time between oral pill and first misoprostol – hours [median (IQR)]*	42.8 (9.0)	42.5 (9.4)
Another dose of misoprostol [N (%)]	23 (21.9)	24 (23.3)
Total doses of misoprostol [median (IQR)]	1 (0)	1 (1)
Time to follow-up – weeks [median (IQR)]		
First follow-up	2.6 (1.0)	2.4 (1.0)
Second follow-up	(N=28) 4.5 (3.5)	(N=32) 4.0 (3.2)
After menses [N (%)]	9 (32.1)	13 (40.6)
Time to complete miscarriage – weeks [median (IQR)]	3 (1.86)	2.7 (1.43)

* 5 and 6 missing values in mifepristone group and misoprostol-alone group, respectively (timing do not specified by the participants on questionnaire).

Table 3 – Clinical outcomes related to the success of medical treatment.		
Outcome [N (%)]	**Mifepristone Group (N=105)**	**Misoprostol-Alone Group (N=103)**
Complete miscarriage at 1st follow-up	76 (72.4)	68 (66.0)
Incomplete | Missed	28 (26.7) | 1 (1.0)	27 (26.2) | 8 (7.8)
Complete miscarriage at 2nd follow-up	94 (89.5)	83 (80.6)
Incomplete | Missed	10 (9.5) | 1 (1.0)	17 (16.5) | 3 (2.9)
Overall success	99 (94.3)	85 (82.5)
Incomplete | Missed	5 (4.8) | 1 (1.0)	15 (14.6) | 3 (2.9)
Uterine aspiration/curettage	6 (5.7)	15 (14.6)*

* 3 cases not accounted as complete miscarriage were not proposed for surgical treatment.

Table 4 – Treatment complications diagnosed during the follow-up, adverse events and symptoms intensity reported by participants after completed the initial treatment (oral mifepristone or placebo followed by vaginal misoprostol).		
Event	**Mifepristone Group (N=105)**	**Misoprostol-Alone Group (N=103)**
Treatment complications [N (%)]		
Bleeding resulting in moderate to severe anemia*	2 (1.9)	4 (3.9)
Pelvic infection (uncomplicated)	1 (1)	0 (0)
Adverse events [N (%)]†		
Nausea	36 (34.6)	24 (23.8)
Vomiting	22 (21.2)	16 (15.8)
Diarrhea	32 (30.8)	27 (26.7)
Headache	40 (38.5)	34 (33.7)
Dizziness	34 (32.7)	25 (24.8)
Chills	30 (28.8)	32 (31.7)
Fever	4 (3.8)	2 (2.0)
Symptoms intensity [median (IQR)]		
Vaginal bleeding	4 (2)	4 (2)
Abdominal pain	4 (2)	4 (1)
Analgesics use [N (%)]†	94 (90.4)	84 (83.2)

* 5 women treated with intravenous iron, 1 woman of the misoprostol-alone group treated with transfusion of 2 units of red blood cells.
† 1 and 2 missing values in mifepristone group and misoprostol-alone group, respectively (questionnaire incompletely fulfilled by participants).

Table 5 – Treatment acceptability reported by participants after completed the initial treatment (oral mifepristone or placebo followed by vaginal misoprostol).		
Event	**Mifepristone Group (N=105)**	**Misoprostol-Alone Group (N=103)**
Satisfaction [N (%)]*		
Bad or indifferent	32 (32.3)	21 (21.2)
Good	67 (67.7)	78 (78.8)
Recommendation to a friend on the same clinical situation [N (%)]†	92 (92.0)	87 (91.6)

* 8 and 4 missing values in mifepristone group and misoprostol-alone group, respectively (questionnaire incompletely fulfilled by participants).
† 5 and 8 missing values in mifepristone group and misoprostol-alone group, respectively (questionnaire incompletely fulfilled by participants).