

1 Mifepristone Antagonization With Progesterone to Prevent Medical Abortion: A Randomized
2 Controlled Trial

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39 **Précis**

40 Mifepristone ingestion without subsequent misoprostol administration in first-trimester

41 gestations can result in hemorrhage and poses safety concerns.

42 **Abstract**

43 **Objective:** To estimate the efficacy and safety of mifepristone antagonization with high-dose
44 oral progesterone.

45 **Methods:** We planned to enroll 40 women in a double-blind, placebo-controlled, randomized
46 trial. We enrolled women 44-63 days gestation with ultrasound-confirmed gestational cardiac
47 activity planning surgical abortion. Participants ingested mifepristone 200 mg and initiated oral
48 progesterone 400 mg or placebo 24 hours later twice daily for 3 days, then once daily until their
49 planned surgical abortion 14-16 days after enrollment. Follow-up visits were scheduled 3 ± 1 , 7 ± 1
50 and 15 ± 1 days after mifepristone intake with ultrasonography and blood testing for human
51 chorionic gonadotropin and progesterone. Participants exited from the study when they had their
52 surgical abortion or earlier for gestational cardiac activity absence, gestational sac expulsion or
53 medically indicated suction aspiration. We assessed the primary outcome of continued
54 gestational cardiac activity at approximately two weeks (15 ± 1 days), side effects after drug
55 ingestion, and safety outcomes including hemorrhage and emergent treatment.

56 **Results:** We enrolled participants from February to July 2019 and stopped enrollment after 12
57 patients for safety concerns. Mean gestational age was 52.5 days. Two (one per group)
58 voluntarily discontinued 3 days after mifepristone ingestion for subjective complaints (nausea
59 and vomiting, bleeding). Among the remaining 10 women (5 per group), gestational cardiac
60 activity continued for two weeks in 4 in the progesterone group and 2 in the placebo group. One
61 woman in the placebo group had no gestational cardiac activity 3 days after mifepristone use.
62 Severe hemorrhage requiring ambulance transport to hospital occurred in 3 patients; 1 received
63 progesterone (complete expulsion, no aspiration) and 2 received placebo (aspiration for both, one

64 required transfusion). We halted enrollment after the third hemorrhage. No other significant side
65 effects were reported.

66 **Conclusion:** We could not estimate the efficacy of progesterone for mifepristone antagonization
67 due to safety concerns when mifepristone is administered without subsequent prostaglandin
68 analogue treatment. Women in early pregnancy who use only mifepristone may be at high risk of
69 significant hemorrhage.

70 **Clinical Trial Registration:** [ClinicalTrials.gov, NCT03774745](https://clinicaltrials.gov/ct2/show/study/NCT03774745).

71

72 **Introduction**

73 In the United States, approximately 862,000 abortions occur per year of which almost
74 40% occur using medical abortion (1). The treatment approved by the Food and Drug
75 Administration (FDA) for medical abortion is a combination of mifepristone and misoprostol
76 through 70 days gestation (2). Mifepristone acts as a competitive progesterone receptor
77 antagonist **and promotes decidual necrosis to weaken implantation, enhances uterine sensitivity**
78 **to prostaglandins, and softens the cervix (3)**. Accordingly, mifepristone has some activity to
79 induce abortion when used alone. However, overall efficacy is generally 80% or less and these
80 studies typically included women less than 49 days gestation (4). Medical abortion efficacy is
81 improved significantly with the addition of a prostaglandin analogue (4). Mifepristone followed
82 in 24-48 hours by misoprostol is 96-97% effective through 70 days gestation; however, as
83 gestation advances from 49 to 70 days, complete abortion rate decreases and continuing
84 pregnancy rate increases (2). Approximately 0.3% of women at 49 days or less experience a
85 continuing pregnancy compared to 3.1% of women at 64 to 70 days (2). A recent United
86 Kingdom study of women who initiated medical abortion at 64 to 70 days found that 9/89 (10%)
87 women with continuing pregnancies detected at follow-up opted to continue the pregnancy (5).

88 Case series have reported that some women may change their minds about terminating
89 their pregnancies after ingesting mifepristone and prior to misoprostol treatment (6-8). Although
90 an exact proportion is unknown, the best estimate is that <0.005% of women who use
91 mifepristone choose to continue their pregnancies (9). Because mifepristone binds strongly to the
92 progesterone receptor and has a long half-life (4), some scientists believe that this action is
93 potentially irreversible. However, others have questioned this theory and believe that providing

94 high doses of progesterone may antagonize the effects of mifepristone when administered for
95 abortion (6).

96 No clinical trials have been performed to adequately study antagonizing mifepristone
97 with progesterone treatment. Case series reported to date have significant limitations, including
98 using investigational treatment (high-dose progesterone) following mifepristone ingestion
99 without consenting women for this experiment, incomplete reporting of outcomes, use of varying
100 progesterone doses, routes and durations, and lack of control groups to understand true efficacy
101 (6-8). The largest case series (547 women evaluated) reported a 48% continuing pregnancy rate
102 using various progesterone regimens, with the highest rates (64-68%) using various
103 intramuscular or oral treatments (8). To address these issues, we conducted a double-blind
104 placebo-controlled randomized trial to evaluate continuing pregnancy rates, safety, and side
105 effects of high-dose oral progesterone in women who used mifepristone during early pregnancy.

106

107

108 **Methods**

109 We conducted this randomized, double-blind, placebo-controlled trial at the University of
110 California, Davis Medical Center. We approached women who had completed counseling and
111 consent for a surgical abortion and were 63 days gestation or less about study participation.
112 Inclusion criteria were 18 years or older, English-speaking, singleton pregnancy, and willingness
113 to delay the abortion by approximately two weeks. Exclusion criteria were medical
114 contraindications to medical abortion per the mifepristone FDA label (2), an allergy to
115 mifepristone or progesterone, or a peanut allergy (on-label contraindication to oral progesterone).

116 The UC Davis Institutional Review Board approved this study and all participants gave written
117 study consent prior to beginning any study procedures.

118 The screening visit included obtaining study consent, recording demographic
119 information, soliciting baseline pregnancy symptoms (subjectively rated as none, mild, moderate
120 or severe), and inquiring if they had used mifepristone or progesterone previously. Patients for
121 whom transvaginal ultrasonography demonstrated gestational cardiac activity and a gestational
122 age 44-63 days gestation based on Goldstein and Wolfson's criteria (10) could enroll that day.
123 Women less than 44 days gestation at screening returned for enrollment, at which time
124 transvaginal ultrasonography was repeated to confirm gestational cardiac activity and gestational
125 age.

126 Enrolled participants had blood drawn for human chorionic gonadotropin (hCG) and
127 progesterone levels, then swallowed mifepristone 200 mg in front of an investigator. Study
128 treatment (progesterone or placebo) was prepared by the UC Davis Investigational Drug Service
129 (IDS) by placing 38 capsules of progesterone 200 mg or similar-appearing placebo capsules in
130 opaque pill containers. The IDS could not over-encapsulate the drugs due to product size. The
131 IDS performed the randomization allocation using a computer-generated random sequence in
132 blocks of four, sequentially numbered the containers, and maintained the randomization log to
133 ensure drug allocation concealment until study completion. Participants were instructed to start
134 study treatment 24 hours after mifepristone ingestion by taking two capsules twice daily for three
135 days then two capsules once daily until the study exit visit. We chose this dosing regimen
136 because it was the most effective option previously described in a case series of mifepristone
137 antagonization (8). Participants received a diary to document any side effects and capsule intake.

138 Participants also received the standard medical abortion bleeding and side effect instructions
139 distributed to medical abortion patients at the University of California, Davis.

140 Research staff contacted participants 24 hours after mifepristone administration to
141 confirm the start of study treatment. Follow-up visits were scheduled 3 ± 1 , 7 ± 1 and 15 ± 1 days
142 after mifepristone intake. Each visit included diary review, assessment of symptoms/drug side
143 effects, ultrasonography to establish presence or absence of gestational cardiac activity, and
144 blood testing for hCG and progesterone. Additionally, a research coordinator independently
145 counted unused study drug to maintain investigator blinding. The subject's planned surgical
146 abortion was scheduled concurrent with her last study visit. Participants exited from the study
147 when they had their surgical abortion, or earlier for gestational cardiac activity absence,
148 gestational sac expulsion, or medically-indicated suction aspiration. At the final visit,
149 participants were asked if they knew what treatment they received or looked up the capsules
150 online for identification.

151 The primary outcome was continuing pregnancy with presence of gestational cardiac
152 activity after approximately two weeks (15 ± 1 days). Secondary outcomes included expulsion
153 rates over two weeks, change in hCG and progesterone during treatment, study drug side effects,
154 and safety outcomes (e.g., hemorrhage, emergency department visit, emergent suction
155 aspiration). Safety evaluations (adverse events review) were performed by the principal
156 investigator after each subject completed the study and at research review meetings every two
157 weeks by the primary study team. The principal investigator was responsible for continued safety
158 oversight and decisions to stop the study for safety reasons.

159 We estimated a 68% continuing pregnancy rate with oral progesterone treatment based on
160 a report using the same dosing after mifepristone administration in early pregnancy, stating that

161 68% of women had a pregnancy that continued to 20 weeks or more (8). We also estimated that
162 only 25% of women receiving placebo would have a continuing pregnancy (10). Using 80%
163 power and $\alpha=0.05$, 20 participants per group were required.

164 We performed an intention-to-treat analysis, using Fisher's Exact Test or Chi-square test
165 as indicated, t-test for continuous variables and Mann Whitney U for comparing median values.

166

167 **Results**

168 We enrolled 12 women from February to July 2019 (Figure 1). Patient characteristics are
169 presented in Table 1. Two women exited the study voluntarily related to side effects; both had a
170 suction aspiration 3 days after mifepristone administration. The first, in the placebo group, was
171 48 days at enrollment and had a prior medical abortion. She had increased anxiety about bleeding
172 that started 2 days after mifepristone use and requested a suction aspiration. The second, in the
173 progesterone group, had three prior pregnancies and mild nausea and vomiting at baseline. She
174 had developed increasing nausea and vomiting after enrolling, resulting in dehydration that
175 required intravenous fluids as an outpatient. She only took two of her four treatment doses before
176 requesting a suction aspiration.

177 Overall, 4/6 women in the progesterone group and 2/6 women in the placebo group had a
178 continuing pregnancy at two weeks. Excluding the two women who did not finish treatment,
179 these rates are 4/5 and 2/5 respectively. A detailed listing of individual subject characteristics
180 and outcomes is included in Appendix 1, available online at <http://links.lww.com/xxx>.

181 Four pregnancies did not continue, including one subject at 48 days in the placebo group
182 who had no gestational cardiac activity 3 days after mifepristone use and had an uneventful
183 suction aspiration. Three other women had severe bleeding requiring ambulance transport to an

184 emergency department. The first subject received progesterone treatment after enrollment at 56
185 days gestation. She reported no bleeding at the first follow-up visit 2 days post mifepristone.
186 Shortly after her visit, she started having brisk bleeding and called an ambulance. Transvaginal
187 ultrasound in the emergency department found no gestational sac and a heterogenous
188 endometrial lining of approximately 1.5 cm. Heavy bleeding lasted about 3 hours overall and no
189 intervention was needed. The second subject received placebo and enrolled at 60 days gestation.
190 She noted new mild bleeding at a follow-up visit two days after mifepristone use. The following
191 day, she called an ambulance due to onset of heavy vaginal bleeding. In the emergency
192 department, a study physician found significant heterogenous material in the uterine cavity on
193 ultrasound exam with continued brisk bleeding, so a suction aspiration was performed. Pathology
194 demonstrated normal chorionic villi. The third subject also received placebo and enrolled at 60
195 days gestation. She noted new mild spotting at a follow-up visit two days after mifepristone use.
196 The following days, she called an ambulance after experiencing hemorrhage. In the emergency
197 department, a study physician evaluated the subject who had significant brisk bleeding,
198 hypotension and tachycardia. Transvaginal sonography showed the gestational sac still in the
199 uterine cavity, so an emergent suction aspiration was performed. This subject's hemoglobin
200 decreased in the emergency department from 9.2 to 7.5 gm/dL and she received a one-unit
201 transfusion of packed red blood cells. At safety contacts two and four weeks later, the subject
202 reported no issues. We stopped enrollment for safety reasons after the third subject required
203 emergent evaluation and a transfusion.

204 Baseline and follow-up serum hCG and progesterone levels are presented in Figures 2
205 and 3, respectively. Median baseline hCG and progesterone levels for the progesterone group
206 were 76,776 mIU/mL (range 21,062-126,647 mIU/mL) and 12.4 ng/mL (range 10.5-24.0

207 ng/mL), respectively. Median baseline hCG and progesterone levels for the placebo group were
208 153,908 mIU/mL; range 25,450-246,638 mIU/mL) and 16.3 ng/mL (range 11.2-18.9 ng/mL),
209 respectively. In the progesterone group, progesterone levels increased 240-1010% within a few
210 days of starting treatment among women with continuing gestational cardiac activity at two
211 weeks whereas the one subject with hemorrhage demonstrated an increase of only 45% despite
212 being adherent with study drug instructions.

213 Table 2 describes side effects related to pregnancy or treatment. One subject in the
214 progesterone group noted the onset of severe nausea and vomiting shortly after mifepristone
215 intake that preceded progesterone treatment; otherwise, no appreciable differences in
216 development of new severe side effects were identified between treatment groups. All women
217 experienced some spotting (n=8) or bleeding (n=9) during treatment except for the subject with
218 the highest baseline progesterone (24.1 ng/mL).

219 Only two participants believed they received progesterone, of whom one did (continuing
220 pregnancy at two weeks) and one did not (hemorrhage requiring emergent aspiration). The
221 remaining ten women were evenly split between placebo and unsure. None of the women looked
222 on the internet to identify the study capsules they received.

223

224 **Discussion**

225 Although the study sample size was powered to demonstrate a difference in continuing
226 pregnancy rates between progesterone and placebo treatment after mifepristone ingestion, we
227 could not evaluate this outcome due to stopping enrollment for safety reasons. However, we can
228 make a few global and important conclusions from this very small, randomized trial. First,
229 women who receive high-dose oral progesterone treatment do not experience side effects that are

230 noticeably different than placebo. Although women using progesterone did report worsening of
231 some pregnancy symptoms, like vomiting and tiredness, these issues were rarely severe.

232 Second, and most importantly, are the lessons about treatment safety. Providing treatment
233 in any medical situation requires a full understanding of the potential benefits and risks. Previous
234 case series reports do not describe outcomes for the one-third or more women without continuing
235 pregnancies after progesterone treatment (8). Three of 12 women enrolled experienced very
236 heavy bleeding resulting in ambulance transport to an emergency department visit, a rate higher
237 than reported with medical abortion in which 0.6% of women may have emergency department
238 visits (12). Women who use mifepristone for a medical abortion should be advised that not using
239 misoprostol could result in severe hemorrhage, even with progesterone treatment. We stopped
240 the study because of these complications and, thus, could not quantify the full extent of this risk.
241 Because of the potential dangers for women who opt not to use misoprostol after mifepristone
242 ingestion, any mifepristone antagonization treatment must be considered experimental.

243 The study has multiple limitations, primarily the inability to safely reach the enrollment
244 goal to fully assess the primary outcome. Additionally, blinding for progesterone capsules is
245 difficult and imperfect; however, we believe we maintained blinding because the women
246 enrolled had never used progesterone and none looked up the treatment to identify the drug. Of
247 note, the variability in progesterone level among women in the progesterone group may be
248 explained by differential oral absorption of progesterone (13). Although one may postulate
249 another route of progesterone administration might affect the outcome, the case reports in the
250 literature suggest similar continuing pregnancy rates after oral and intramuscular treatment (8).

251 Our study established outcomes at two weeks as a surrogate for ongoing pregnancy; as
252 such, it does not capture those who may still experience pregnancy loss more than 2 weeks after

253 mifepristone exposure (14). Accordingly, the outcomes described may not reflect the ultimate
254 rate of pregnancies that continue past 20 weeks gestation. Progesterone levels declined to levels
255 near baseline from these high peaks with continued treatment for two weeks. These findings
256 raise two opposing questions: first, if progesterone can prevent medical abortion following
257 mifepristone, is treatment necessary for more than two weeks? The case report from which the
258 oral progesterone regimen for this study was based used the treatment through the “end of the
259 first trimester” (8). Second, do those treated with placebo just expel the pregnancy earlier than
260 those that receive progesterone but no overall long-term difference in continuing pregnancy
261 exists?

262 The context of this study is the question of whether a woman who has taken mifepristone
263 200 mg for a medical abortion and decides not to proceed with misoprostol treatment will be less
264 likely to expel the pregnancy if she receives high-dose progesterone as compared to no
265 treatment. Although mifepristone can cause abortion when used by itself in early pregnancy, the
266 exact rate is not clear because studies were small and limited primarily to pregnancies of 49 days
267 or less. Medical abortion today is used through 70 days gestation. Additionally, a background
268 rate of pregnancy loss is present regardless of mifepristone treatment. In women with gestational
269 cardiac activity demonstrated by ultrasonography at 6-10 weeks, 13.4% will spontaneously have
270 an early pregnancy loss (15).

271 This study, although small, provides important insight into the safety of mifepristone
272 antagonization with progesterone during early pregnancy. We should not dismiss mifepristone
273 antagonization as impossible; fully understanding outcomes will serve as the best means to
274 accurately inform our patients, the medical community, and legislators. Existing literature before
275 this study is comprised of case reports and series which are not evidence of efficacy and do not

276 address safety (6-8). This level of evidence is inadequate to support or refute the benefits and
277 risks of any treatment. Unfortunately, legislators often fail to understand differences in level of
278 evidence and some states now require physicians who provide medical abortion to counsel
279 women that the actions of mifepristone can be reversed if they change their mind. In 2015,
280 Arkansas implemented mandatory abortion reversal counseling followed by Arizona (later
281 repealed in 2016), South Dakota, Utah, Idaho and, most recently, North Dakota. Several other
282 states have introduced and passed legislation, although some were vetoed by the Governor.
283 Abortion is no different than any other medical treatment when considering clinical practice
284 guidelines; laws should not mandate counseling or provision of any treatment when we don't
285 fully understand treatment efficacy (including best route of administration, dose and duration)
286 and safety.

287 The dilemma that has been created around mifepristone antagonization only exists
288 because of the void in high-quality research addressing the issue. For now, such a treatment is
289 experimental and should only be offered in Institutional Review Board approved human clinical
290 trials to ensure proper oversight.

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Creinin
18

329 **Legend**

330 **Figure 1.**

331 Title:

332 Participant flow in women who received mifepristone 200 mg followed by progesterone for up to
333 two weeks

334 Footer:

335 GCA: gestational cardiac activity

336 **Figure 2.**

337 Title:

338 Serum hCG levels in women who received mifepristone 200 mg followed by progesterone for up
339 to two weeks

340 Footer:

341 hCG: human chorionic gonadotropin

342 * Participants experiencing hemorrhage

343 † Participant experienced loss of gestational cardiac activity

344 ‡ Value >270,000 (upper limit of hCG test)

345 ¥ Discontinued related to side effects

346 **Figure 3.**

347 Title:

348 Progesterone levels in women who received mifepristone 200 mg followed by progesterone
349 (Figure A) or placebo (Figure B) for up to two weeks

350 Header Figure 2A: Progesterone users

351 Header Figure 2B: Placebo users

352 Footer:

353 * Participants experiencing hemorrhage

354 † Participant experienced loss of gestational cardiac activity

355 ‡ Discontinued related to side effects.

356

Authors' Data Sharing Statement

Will individual participant data be available (including data dictionaries)? *Yes.*

What data in particular will be shared? *Data included with the submission in Appendix 1, available online at <http://links.lww.com/xxx>*

What other documents will be available? *No.*

When will data be available (start and end dates)? *With publication.*

By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? *In Appendix 1, <http://links.lww.com/xxx>.*

358 Table 1. Characteristics at enrollment for women receiving mifepristone and randomized to
 359 progesterone or placebo treatment

Characteristic	Total N=12	Progesterone n=6	Placebo n=6
Age (years)	27.3 (20.9-39.6)	29.8 (24.6-39.6)	24.1 (20.9-33.8)
Gestational age (days)	52.5 (47-61)	49.5 (47-56)	55 (48-61)
Body Mass Index (kg/m²)	24.6 (19.0-52.3)	24.8 (19.0-36.4)	24.6 (22.7-52.3)
Obese (≥ 30.0)	4 (33%)	2 (33%)	2 (33%)
Race			
White	3 (25%)	0	3 (50%)
Black or African American	5 (42%)	4 (67%)	1 (17%)
Asian	4 (33%)	2 (33%)	2 (33%)
Ethnicity			
Hispanic or Latina	2 (17%)	1 (17%)	1 (17%)
Marital Status			
Never married	7 (58%)	3 (50%)	4 (67%)
Married	2 (17%)	1 (17%)	1 (17%)
Divorced/Separated	3 (25%)	2 (33%)	1 (17%)
Education Level			
High School Graduate	2 (17%)	0	2 (33%)
Some college	9 (75%)	5 (83%)	4 (67%)
College Graduate	1 (8%)	1 (17%)	0
Gravidity			
>3 prior pregnancies	4 (1-12) 7 (58%)	4.5 (1-10) 4 (67%)	3.5 (1-12) 3 (33%)
Parity			
Nulliparous	1 (0-6) 4 (33%)	1.5 (0-6) 1 (17%)	0.5 (0-3) 3 (33%)

Prior Abortion	9 (75%)	4 (67%)	5 (83%)
>3 prior abortions	4 (33%)	2 (33%)	2 (33%)
Past Mifepristone Use	4 (733%)	1 (17%)	3 (33%)
Prior Progesterone Use	0	0	0

361 Data are presented as n (%) or median (range)

362 Table 2. Side effects* noted during follow-up of women in early pregnancy receiving mifepristone and randomized to progesterone or
 363 placebo treatment for up to two weeks

364

	Reported at Baseline		Increased from Baseline [†]		Increased to severe during follow-up [†]	
	Progesterone n=6	Placebo n=6	Progesterone n=6	Placebo n=6	Progesterone n=6	Placebo n=6
Nausea	4 (67%)	5 (83%)	2 (33%)	2 (33%)	2 (33%)	1 (17%)
Vomiting	2 (33%)	3 (50%)	4 (67%)	0	2 (33%)	0
Mastalgia	4 (67%)	5 (83%)	1 (17%)	0	0	0
Tiredness	5 (83%)	4 (67%)	3 (50%)	0	0	1 (17%)
Mood changes	4 (67%)	5 (83%)	0	0	1 (17%)	0
Reflux	2 (33%)	2 (33%)	1 (17%)	0	0	0
Dizziness	2 (33%)	1 (17%)	0	0	0	0
Bleeding	0	0	4 (67%)	4 (67%)	1 (17%)	3 (50%)
Spotting	1 (17%)	1 (17%)	3 (50%)	4 (67%)	0	0
Cramping	3 (50%)	2 (33%)	4 (67%)	5 (83%)	0	0

365

366 * subjectively assessed by participant as none, mild, moderate or severe

367 † at any time during follow-up

368 Data are presented as n (%)

Appendix. Individual subject characteristics at enrollment and outcomes for women receiving mifepristone 200 mg and randomized to progesterone or placebo treatment

Subject Number	Study group*	Age (years)	Gestational Age (days)	Race	Ethnicity	Education	Marital Status	Smoking	Alcohol	Marijuana Use	Drug Use	Total Pregnancies	Vaginal Delivery	Cesarean Delivery	Miscarriages	Abortions	Weight (kg)	BMI (kg/m ²)
1	Progesterone	24.6	53	Asian	Not Hispanic	Some college	Never married	Never	Never	Never	Never	1	0	0	0	0	84.2	32.9
2	Progesterone	30.9	50	Black	Not Hispanic	Some college	Separated	Never	Current	Current	Never	8	3	0	0	4	68.9	23.8
3	Placebo	20.9	50	Asian	Not Hispanic	Some college	Never married	Never	Never	Never	Never	1	0	0	0	0	61.8	24.1
4	Placebo	22.6	48	White	Hispanic	Some college	Married	Current	Current	Current	Current	2	0	0	0	1	152.0	52.3
5	Progesterone	39.6	49	Black	Not Hispanic	Some college	Never married	Current	Never	Never	Never	5	2	0	0	2	51.8	19.0
6	Placebo	24.8	61	Asian	Not Hispanic	Some college	Never married	Never	Current	Current	Never	3	0	0	1	1	66.7	24.4
7	Placebo	23.5	48	White	Not Hispanic	High School graduate	Never married	Former	Never	Current	Never	7	0	1	0	5	71.8	22.7
8	Progesterone	27.7	56	Black	Not Hispanic	Some college	Never married	Never	Current	Never	Never	10	1	0	1	7	100.8	36.4
9	Progesterone	31.9	47	Asian	Not Hispanic	College graduate	Married	Never	Never	Never	Never	4	0	2	1	0	66.0	25.8
10	Placebo	27.0	60	Black	Not Hispanic	High School graduate	Never married	Never	Current	Current	Never	4	2	0	0	1	63.5	24.8
11	Placebo	33.8	60	White	Not Hispanic	Some college	Separated	Current	Former	Former	Former	12	6	0	0	5	105.5	34.3
12	Progesterone	28.6	48	Black	Hispanic	Some college	Divorced	Never	Current	Current	Never	3	1	0	0	1	53.8	19.7

Subject Number	hCG (mIU/mL)	Progesterone (ng/mL)	Exit Study Day [†]	FINAL OUTCOME	Hospital visit	Reason for Hospital visit
1	95,870	12.1	17	Continuing GCA at exit visit	No	N/A
2	57,681	11.5	16	Continuing GCA at exit visit	No	N/A
3	113,431	18.9	16	Continuing GCA at exit visit	No	N/A
4	25,450	13.7	4	No GCA at follow-up visit	No	N/A
5	107,780	24.1	16	Continuing GCA at exit visit	No	N/A
6	246,638	18.9	16	Continuing GCA at exit visit	No	N/A
7	73,018	11.2	4	D&C requested (bleeding, anxiety)	No	N/A
8	126,647	12.6	3	Expelled pregnancy, no D&C	Yes (ER), Day 3	Hemorrhage, hemoglobin 10.4 gm/dL
9	39,660	10.5	4	D&C requested (nausea, vomiting)	Yes (L&D), Day 3	Dehydration, nausea, vomiting
10	230,220	16.3	5	Expelled pregnancy, incomplete, emergent D&C	Yes (ER), Day 5	Hemorrhage, hemoglobin 9.6 gm/dL
11	194,384	16.7	6	Expelled pregnancy, incomplete, emergent D&C, transfusion	Yes (ER), Day 6	Hemorrhage, hemoglobin change 9.2 to 7.5 gm/dL
12	21,062	13.9	15	Continuing GCA at exit visit	No	N/A

BMI: body mass index; GCA: gestational cardiac activity; ER: emergency room; L&D: labor and delivery; N/A: not applicable

* Initiated on study day 2 (24 hours after mifepristone ingestion)

[†] Day 1: day of mifepristone administration





