

First of its kind study seeks to answer whether effects of 'abortion pill' can be reversed

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Women who initiate medical abortion but opt to stop in the middle of treatment may be at risk for serious blood loss, a UC Davis Health study finds. Researchers found this is true even for women who use an experimental treatment that claims to "reverse" the effects of the abortion pill. The study, published today in *Obstetrics and Gynecology*, provides important insights into the safety of using high doses of progesterone during early pregnancy to try to stop a medical abortion.

Medical [abortion](#) involves using two medicines in sequence: [mifepristone](#) and misoprostol. This combination is approved by the Food and Drug Administration (FDA) for [medical abortion](#) during the first 70 days of [pregnancy](#). When mifepristone is followed in 24-48 hours by misoprostol, the abortion regimen is highly effective and safe.

The first randomized clinical study on medical abortion "reversal"

Anti-abortion activists claim that women who take mifepristone for abortion and change their mind before using misoprostol can take progesterone to stop the abortion process. The UC Davis Health study is the first randomized [clinical study](#) to test the efficacy of progesterone after mifepristone. The process of reversing mifepristone's binding to progesterone receptors is referred to medically as mifepristone antagonization.

Before this study, the medical literature on mifepristone antagonization consisted of non-peer reviewed case reports and series, which do not provide evidence of how effective and safe the progesterone treatment is.

The UC Davis Health study sought to determine whether a woman who has taken 200 milligrams of mifepristone—the first medicine in the medical abortion process—will be less likely to expel the pregnancy if she receives high-dose progesterone as compared to placebo treatment. The study enrolled women planning a surgical abortion who were willing to delay the procedure for two weeks. Women were followed for up to two weeks after taking mifepristone to identify if the pregnancy continued to develop. Those with continuing pregnancies had a surgical abortion as scheduled.

"We planned to enroll 40 women, but stopped the study due to safety concerns," said Mitchell Creinin, leading author, professor of obstetrics and gynecology and director of Family Planning at UC Davis Health.

After enrolling 12 women, three participants experienced severe hemorrhage complications, requiring ambulance transport to an emergency department. One of the women had received progesterone and two had received placebo. Because of these [safety issues](#), Dr. Creinin and his

co-investigators stopped the study early.

Since the study was cut short, researchers could not quantify the full extent of the hemorrhage risk. Still, the study provides important insight into the safety of using progesterone once mifepristone is administered in early pregnancy.

"Women who use mifepristone for a medical abortion should be advised that not following up with misoprostol could result in severe hemorrhage, even with progesterone treatment," Creinin said.

Overall, four of the six women in the progesterone group and two of the six women in the placebo group had a continuing pregnancy at two weeks and had surgical abortions as planned. The authors say these numbers are too small to make conclusions about comparing the outcomes, which could be attributed to random chance.

Policy implications of the study

Some states in the U.S. require physicians who provide medical abortion to inform [women](#) that if they change their mind after taking mifepristone, a treatment (progesterone) is available to ensure the pregnancy will continue. There is no scientific consensus that supports this claim.

"For now, the level of evidence is still inadequate to support or refute the benefits and risks of progesterone treatment in reversing abortion initiated by mifepristone," Creinin said. "Laws should not mandate counseling or provision of any treatment that claims to reverse abortion when both its efficacy and safety are unclear."

The researchers propose that [progesterone](#) treatment to reverse the mifepristone pill is human experimentation and should only be offered in Institutional Review Board-approved clinical trials to ensure proper design, reporting and oversight.

Provided by University of California - Davis Health

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