RESEARCH SUMMARY

ULIPRISTAL FOR EARLY MEDICATION ABORTION
A PROOF-OF-CONCEPT STUDY

Gynuity Health Projects has been conducting exploratory clinical research into existing medicines that might offer an improvement to a misoprostol-only regimen and an alternative to a combined mifepristone-misoprostol regimen, the current recognized clinical standard for outpatient first trimester medication abortion. Ulipristal acetate has a similar chemical structure to mifepristone. It is widely available globally and is already established as a safe, effective method of emergency contraception within five days after unprotected intercourse or when contraception might have failed. Our two-stage study assessed the possibility of ulipristal instead of mifepristone in a combined regimen with misoprostol for medication abortion through 63 days' gestation.

About the Study

We first evaluated two different doses (90 and 60 mg) of oral ulipristal with misoprostol to see if one worked better and, because they showed similar efficacy and safety profiles, we then continued to evaluate the lower dose.

Participants attending the outpatient clinic of a public maternal hospital in Mexico City swallowed two 30 mg pills of ulipristal in-clinic and after a brief period of observation were discharged with four 200 mcg pills of misoprostol. They were counseled to self-administer the misoprostol 24 hours after the ulipristal, holding two pills in each cheek for 30 minutes before swallowing any remaining bits. They then returned to the clinic over one week later to determine the status of the abortion and answer a series of questions about their experiences using the study medications and the acceptability of the regimen.

Study Regimen

60 mg oral ulipristal followed by 800 mcg buccal misoprostol 24 hours later

Study Findings

Complete abortion occurred with the study regimen in 129 out of 133 participants. Among those for whom this regimen did not result in pregnancy termination, one had a completion with sharp curettage, two received manual vacuum aspiration, and one underwent a repeat medication abortion with misoprostol alone.

After ulipristal administration, side effects were rare. After taking misoprostol, the most common side effects were chills, diarrhea, and nausea; these side effects are transitory, easily managed, and often associated with misoprostol use. No serious adverse events were reported.

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Key Study Findings

High abortion completion with the study regimen, 97% (95% confidence interval, 94.1 to 99.9%)

High overall satisfaction with the abortion process, 97.7%

Side effects after taking ulipristal were rare

No serious adverse events

Overall satisfaction with the abortion process was high. Among the 133 participants questioned during the follow-up visit, 130 rated the treatment satisfactory or very satisfactory, 113 rated the pain level as acceptable or very acceptable, and 121 said they would recommend the study regimen.

Study Conclusions and Implications

The study provides positive evidence supporting the potential of ulipristal in a combined regimen with misoprostol for safe and effective medication abortion. It has given rise to breakthrough findings that warrant further investigation and provides a basis for future controlled trials comparing ulipristal with traditional medication abortion regimens. We are planning additional studies to gain further insights and explore broader applications of ulipristal in medication abortion.

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Research Article

A proof-of-concept study of ulipristal acetate for early medication abortion. Beverly Winikoff; Manuel Bousiéguez; Jorge Salmerón; Karina Robles-Rivera; Sonia Hernández-Salazar; Angélica Martínez-Huitrón; María Laura García-Martínez; Lucía Aguirre-Antonio; Ilana G. Dzuba. NEJM Evidence 2025; 4(2); Published January 23, 2025; DOI: 10.1056/EVIDoa2400209

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