

Comparison of two doses of ulipristal acetate for medication abortion up to 63 days of gestation

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Registration date 01/09/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/03/2026	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study compares two different doses of ulipristal acetate when used with misoprostol to end early pregnancy of up to 63 days. Mifepristone plus misoprostol is the standard regimen for medication abortion, but mifepristone is not always available in Mexico. Ulipristal acetate is a potential alternative. The aim is to determine whether a lower dose of ulipristal acetate (30 mg) is as effective and safe as a higher dose (60 mg).

Who can participate?

Women aged 18 years or older (including emancipated minors) with an intrauterine pregnancy of up to 63 days, confirmed by ultrasound, who request a legal medication abortion in Mexico City and meet clinical eligibility criteria.

What does the study involve?

Participants are randomly assigned to receive either one 30 mg tablet of ulipristal acetate plus two placebo tablets, or two 30 mg tablets of ulipristal acetate plus one placebo tablet. All participants then take four 200 mcg tablets of misoprostol (800 mcg total) buccally at home 24 hours later. Follow-up takes place 7–10 days later and includes an ultrasound and an interview. The main outcomes assessed are treatment success without surgery or extra medication, safety, and participant satisfaction.

What are the possible benefits and risks of participating?

Participants may benefit from access to a safe and effective abortion regimen under close medical supervision. Risks include expected side effects of the medicines such as cramping, bleeding, nausea, vomiting, diarrhoea, chills, and fever. Serious side effects are uncommon but are monitored closely, and clinical care is provided if needed.

Where is the study run from?

The study is carried out in two maternity hospitals in Mexico City: Hospital Materno Infantil Inguarán and Hospital Materno Infantil Nicolás M. Cedillo.

When is the study starting and how long is it expected to run for?
December 2024 to September 2026

Who is funding the study?
The study is jointly funded by Gynuity Health Projects (New York, USA) and the Secretaría de Salud de la Ciudad de México (SEDESA).

Who is the main contact?
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Additional identifiers

Protocol serial number

1060

Study information

Scientific Title

Randomised, double-blind, placebo-controlled, parallel-group clinical trial to evaluate the efficacy of two regimens of ulipristal acetate in combination with misoprostol for medication abortion in women up to 63 days of gestation

Acronym

ULI-60vs30

Study objectives

Hypothesis: A 30 mg dose of ulipristal acetate, when combined with misoprostol, will have comparable efficacy, safety, and acceptability to the 60 mg dose for medication abortion up to 63 days of gestation.

Primary objective: To compare the efficacy of 30 mg vs 60 mg of ulipristal acetate, followed by buccal misoprostol 800 mcg, for medication abortion.

Secondary objectives: To assess the safety and acceptability of both regimens.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 18/08/2025, Research Ethics Committee, Belisario Domínguez Specialty Hospital (Av. Tláhuac No. 4866, esq. Zacatlán. Col. San Lorenzo Texcoco. Alcaldía Iztapalapa., Mexico City, 09790, Mexico; + 52 55 5850-0000 Ext. 1064; dgpcs.correspondencia@salud.cdmx.gob.mx), ref: 501-010-47-25

Study design

Multicenter interventional double-blinded placebo-controlled parallel-group randomized trial

Primary study design

Interventional

Study type(s)

Efficacy, Safety

Health condition(s) or problem(s) studied

Termination of pregnancy (medication abortion) in women up to 63 days of gestation; unintended pregnancy

Interventions

Intervention group (60 mg): Ulipristal acetate 60 mg orally (two 30 mg tablets) administered under direct supervision in clinic, followed 24 hours later by self-administered buccal misoprostol 800 mcg at home.

Comparator group (30 mg): Ulipristal acetate 30 mg orally (one 30 mg tablet + two placebo tablets) administered under direct supervision in clinic, followed 24 hours later by self-administered buccal misoprostol 800 mcg at home.

Placebo tablets are used to ensure identical appearance of study packages and maintain double blinding.

Randomisation was performed using Stata 18 SE (StataCorp. 2023). A block randomisation scheme with a fixed block size of four was generated separately for each study site. The random number generator was initialised with a fixed seed (20250816) to ensure reproducibility. If enrolment exceeds initial projections at a site, the sequence can be extended by rerunning the program with an updated sample size; in such cases, all prior allocations remain identical to the original scheme, and new allocations are generated in continuation of the same random sequence. The random allocation lists will be used to prepare sequentially numbered, opaque envelopes containing the study medications. Participants will be enrolled sequentially and assigned the next available envelope corresponding to their site.

Intervention Type

Drug

Phase

Phase II/III

Drug/device/biological/vaccine name(s)

Ulipristal acetate, misoprostol

Primary outcome(s)

1. Efficacy — Complete abortion without need for surgical intervention or additional misoprostol measured by proportion of participants with successful medication abortion at follow-up visit (7–10 days after ulipristal administration)
2. Safety — Occurrence of serious adverse events attributable to the study drugs measured by number and proportion of participants with serious adverse events from ulipristal administration until end of follow-up (7–10 days or extended if needed)

Key secondary outcome(s)

Acceptability — Participant-reported satisfaction with the regimen (and willingness to recommend) measured by proportion rating experience as “satisfied/very satisfied” on structured exit interview (Form 3) at follow-up visit 7–10 days after ulipristal (or at extended follow-up, if applicable)

Completion date

30/09/2026

Eligibility

Key inclusion criteria

1. Women aged ≥ 18 years (or emancipated minors)
2. Intrauterine pregnancy confirmed by ultrasound
3. Gestational age ≤ 63 days by ultrasound
4. Eligible for medication abortion under standard clinical criteria
5. Resident in Mexico City
6. Access to a telephone for follow-up
7. Able and willing to provide written informed consent

Participant type(s)

Patient, Service user

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

52 years

Sex

Female

Total final enrolment

0

Key exclusion criteria

1. Liver or renal disease
2. Confirmed or suspected ectopic pregnancy, gestational trophoblastic disease, or undiagnosed adnexal mass
3. Intrauterine device (IUD) in situ
4. Known allergy to ulipristal acetate, misoprostol, or other prostaglandins
5. Unwilling or unable to attend follow-up visit
6. Unable to provide informed consent

Date of first enrolment

01/10/2025

Date of final enrolment

31/08/2026

Locations

Countries of recruitment

Mexico

Study participating centre**Hospital Materno Infantil Inguarán**

Estaño # 307, Col. Felipe Ángeles, Alc. Venustiano Carranza.

Mexico City

Mexico

15310

Study participating centre**Hospital Materno Infantil Nicolás M. Cedillo**

Gustavo Jarmendia esq. Víctor Hernández Covarrubias. Col. Francisco Villa. Alc. Azcapotzalco.

Mexico City

Mexico

02420

Sponsor information

Organisation

Gynuity Health Projects

ROR

<https://ror.org/00swp5c87>

Funder(s)

Funder type

Charity

Funder Name

The OPTions Initiative

Results and Publications

Individual participant data (IPD) sharing plan

Anonymised individual participant data (IPD) will be made available after publication of the main study results in a peer-reviewed journal. Data will include a de-identified dataset and a variable dictionary. Access will be provided only to qualified researchers who submit a formal request, commit to using the data responsibly, protect participant confidentiality, and obtain ethics approval or exemption where applicable. Approval of data sharing requests will be decided by the principal investigators.

IPD sharing plan summary

Available on request