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

Submission date
27/08/2025

Recruitment status
Not yet recruiting

Registration date
01/09/2025

Overall study status
Ongoing

Last Edited
05/09/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 March 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?
Manuel Bousiéguez, (Associate, Gynuity Health Projects), mbousieguez@gynuity.org

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Safety, Efficacy

Participant information sheet

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

Pharmaceutical study type(s)
Dose response

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Ulipristal acetate, misoprostol

Primary outcome measure
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)

Secondary outcome measures
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)

Overall study start date
01/12/2024

Completion date
31/05/2026

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex

Female

Target number of participants
426

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
31/03/2026

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
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Sponsor type
Research organisation

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Funder(s)

Funder type
Charity

Funder Name
The OPTions Initiative

Results and Publications

Publication and dissemination plan
The results of this study will first be shared with the research team and with health authorities of the Secretaría de Salud de la Ciudad de México (SEDESA). Findings will then be presented to relevant stakeholders, including policymakers, clinicians, and representatives of organisations involved in sexual and reproductive health. Results are expected to be disseminated through presentations at national and international scientific conferences and through publication in peer-reviewed scientific journals. A summary of the results will also be uploaded to the clinical trial registry record after completion of the study.

Intention to publish date
30/09/2026

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