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Evaluating ulipristal acetate and misoprostol for induced abortion through 63 days of pregnancy

Submission date
12/08/2022

Recruitment status
No longer recruiting

Registration date
16/08/2022

Overall study status
Completed

Last Edited
27/01/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Abortion with mifepristone and misoprostol is safe, acceptable and effective, and it is recognized worldwide as the first-line treatment for outpatient first-trimester abortion. When mifepristone is not commercially available or difficult to access, misoprostol alone can be used instead, but it is not as effective and is associated with increased side effects because of the need to take more misoprostol. Evidence is required of medication used together with misoprostol that could offer an accessible alternative to the standard treatment. The antiprogestin activity of ulipristal is similar to that of mifepristone and suggests the possibility that together ulipristal and misoprostol could be a safe, acceptable and effective form of medication abortion. The purpose of this study is to identify a treatment schedule for ulipristal followed by misoprostol for induced abortion through 63 days of pregnancy that has minimal complications and is highly acceptable to users. We will evaluate two different doses of ulipristal with misoprostol to see if one works better and then will continue to evaluate the better one to learn more about it.

Who can participate?
Participants residing in Mexico City of at least 18 years old (or emancipated minors) seeking an abortion for a viable pregnancy that is 63 days or less.

What does the study involve?
The study involves swallowing one set of pills (ulipristal) in the clinic and remaining one hour afterwards to respond to questions about any side effects. Twenty-four hours later, participants will self-administer another set of pills (misoprostol) by holding them in their cheeks for 20-30 minutes and then swallowing any remaining bits. Participants will return to the clinic a week later to determine the status of the abortion. If any additional management is needed, the study clinician will provide that. All participants will respond to a series of questions about their experiences using the study medications and the acceptability of the regimen.

What are the possible benefits and risks of participating?
Participants benefit from getting an opportunity to use a new medication abortion method.

Participants will also receive compensation for transportation to/from the clinic. There is no additional direct benefit for participating in the study, however, participants will contribute information that could help future abortion seekers access safe and effective abortion with new combinations of existing medications.
Possible risks are similar to those with standard medication abortion:
1. The method does not work to interrupt the pregnancy. In this case, the clinician can perform a uterine aspiration to complete the abortion.
2. The method interrupts the pregnancy but not completely. Depending on the participant's symptoms, they will be recommended different management options, including waiting more time, taking another dose of misoprostol or having a uterine aspiration.
3. Rarely, very excessive bleeding can result in blood transfusion.
4. Very few users have reported an allergic reaction to the study medications. In case of an allergic reaction after taking ulipristal, the participant will be cared for immediately at the clinical site.
5. Infection is a very rare complication of any abortion method. The study clinician will manage any signs and symptoms of infection with antibiotics and perform a uterine aspiration to complete the abortion.

Where is the study run from?
Participating sites in Mexico City (Mexico)

When is the study starting and how long is it expected to run for?
July 2019 to August 2023

Who is funding the study?
Options for Pregnancy Termination Innovation Initiative ('OPTions Initiative')

Who is the main contact?
Manuel Bousiéguez, mbousieguez@gynuity.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1043

Study information

Scientific Title
Adverse events, acceptability and efficacy of a combined regimen of ulipristal acetate and misoprostol for abortion through 63 days of gestation

Study objectives
We expect that:
1. The adverse events profile of ulipristal and misoprostol will not be inferior to the adverse event profile reported with misoprostol alone
2. Acceptability rates among study participants will be above 90% and similar to those observed with misoprostol alone regimens
3. Efficacy rates will not be inferior to those observed with misoprostol alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 04/07/2022, Research Ethics Committee of the Secretariat of Health of Mexico City (Comité de ética en investigación de la Secretaría de Salud de la Ciudad de México, Avenida Insurgentes #423, Floor 14, Col. Nonoaico Tlatelolco, Del. Cuauhtémoc Ciudad de México, CP 06900; +52 55 51321200 Ext. 1360; ceinc.sedesa@gmail.com), ref: 101-100-041-22
2. Approved 26/06/2023, Research Ethics Committee of the Secretariat of Health of Mexico City (Comité de ética en investigación de la Secretaría de Salud de la Ciudad de México)

Study design

Two-phase sequential intervention study: open-label randomized parallel study followed by one-arm open-label study with historical controls

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Induced abortion

Interventions
Phase 1 of the research will compare two medication regimens with ulipristal acetate and misoprostol: 60 mg UPA orally + 800 mcg misoprostol buccally versus 90 mg UPA orally + 800 mcg misoprostol buccally. Participants will be randomized to the study groups based on a computer-generated assignment.
Phase 2 of the research will continue to evaluate the regimen that demonstrated the best outcomes in Phase 1.

Intervention Type
Drug

Pharmaceutical study type(s)
Dose response

Phase
Phase I/II

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

Primary outcome measure
Adverse events (complications) measured using self-reporting at any point prior to discharge from the study

Secondary outcome measures
Current secondary outcome measures as of 06/08/2024:
1. Side effects measured using self-reporting 1 hour after ulipristal administration and at the scheduled follow-up visit 7-10 later
2. Efficacy measured using a clinical assessment and ultrasound findings of abortion outcome at the scheduled follow-up visit 7-10 days later

3. Acceptability to participants of study medication measured using self-reporting at discharge from the study
4. Pain measured using a scale from 0-10 one hour after ulipristal administration and at the scheduled follow-up visit 7-10 days later

Previous secondary outcome measures:
1. Side effects measured using self-reporting 1 hour after ulipristal administration and at the 1-week follow-up visit
2. Efficacy measured using a clinical assessment of pregnancy viability at the 1-week follow-up
3. Acceptability to participants of study medication measured using self-reporting at discharge from the study
4. Pain measured using a scale from 0-10 one hour after ulipristal administration and at the 1-week follow-up visit

Overall study start date
01/07/2019

Completion date
31/10/2023

Eligibility

Key inclusion criteria
1. Pregnant with estimated gestational age ≤63 days by ultrasound and desiring an abortion
2. Body mass index (BMI) ≤32 kg/m²
3. Aged ≥18 years old or emancipated minor
4. With access to a telephone for follow-up communication
5. Resident of Mexico City
6. Able to provide informed consent

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Female

Target number of participants
Phase 1: 66 participants; Phase 2: 100 participants

Total final enrolment
166

Key exclusion criteria

1. History of hepatic or renal disease
2. Confirmation or suspicion of ectopic pregnancy, gestational trophoblastic disease or undiagnosed adnexal mass
3. IUD in place
4. History of allergy to ulipristal or misoprostol (or other prostaglandins)
5. Unwilling to or with significant difficulty preventing return to clinic for follow up
6. Unable to provide informed consent

Date of first enrolment
31/08/2022

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
Mexico

Study participating centre
Hospital Materno Infantil Inguaran
Estaño # 307, Felipe Ángeles
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Sponsor information

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Sponsor type
Research organisation

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ROR
https://ror.org/00swp5c87

Funder(s)

Funder type
Research organisation

Funder Name
The Options for Pregnancy Termination Innovation Initiative ('OPTions Initiative')

Results and Publications

Publication and dissemination plan
1. Planned publication in a high-impact peer-reviewed journal
2. Presentation at relevant conferences

Intention to publish date
30/11/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/01/2025	27/01/2025	Yes	No