ISRCTN78613350 https://doi.org/10.1186/ISRCTN78613350

Evaluating the use of ulipristal acetate with and without misoprostol for contragestion

Submission date
28/09/2025

Recruitment status
Not yet recruiting

Registration date
15/10/2025

Overall study status
Ongoing

Last Edited
21/10/2026

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 proof-of-concept study will assess the safety, efficacy, and acceptability of use of ulipristal acetate (UPA) with and without misoprostol for prevention and/or disruption of early pregnancy processes through 35 days since the last menstrual period (LMP). Although UPA is known to be effective when used before ovulation for pregnancy prevention, and recent evidence suggests it is highly effective when used with misoprostol for termination of confirmed pregnancies up to 63 days LMP, its potential for pregnancy prevention and/or disruption in the initial post-ovulatory period through 35 days LMP has not been studied in humans. If either regimen is shown is found to be safe, effective and acceptable when used as a contragestive through 35 days LMP, this would fill an important gap in available fertility control methods.

Who can participate?
Women at risk of unwanted pregnancy who are between the ages of 18 and 39 years, over 5 days since unprotected intercourse and 35 days or less since the last menstrual period (LMP)

What does the study involve?
Participants will provide a blood sample at the time of enrollment and will then be randomly assigned to receive either 60 mg of ulipristal acetate followed by 800 mcg misoprostol 24 hours later, or 60 mg of ulipristal acetate followed by placebo pills 24 hours later. Follow-up takes place at the study clinic approximately 14 days after taking the ulipristal acetate and includes a pregnancy test and exit interview and, for those with a positive test result, an ultrasound. The main outcomes assessed are pregnancy status at follow-up, safety and patient satisfaction.

What are the possible benefits and risks of participating?
Participants may benefit from access to a safe and effective option for pregnancy prevention and /or disruption under close medical supervision. Risks include expected side effects of the medications, including cramps, bleeding, nausea, vomiting, chills and fever. Serious side effects are rare but monitored closely, and clinical care is provided if needed.

Where is the study run from?
The study is carried out in one maternity hospital in Mexico City (Hospital Materno Infantil Inguarán) and three private clinics in Mexico City (Cuidado Integral de la Mujer, Gineclinic, S.C., Integra, MDK, and Centro Médico Mujer).

What is the study starting date and how long is it expected to run for?
October 2024 to December 2027

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

Who is the main contact?
Wendy Sheldon, wsheldon@vergeresearch.org

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Wendy Sheldon

Contact details
41 Purdy Avenue #663
Rye
United States of America
10580
+1 (0)9172879052
wsheldon@vergeresearch.org

Additional identifiers

Protocol serial number
1001

Study information

Scientific Title
Safety, efficacy and acceptability of ulipristal acetate with and without misoprostol for contragestion through 35 days LMP

Study objectives
To evaluate the safety, efficacy, and acceptability of using 60 mg of ulipristal acetate, alone or in combination with 800 mcg of misoprostol, for preventing and/or terminating unwanted pregnancy up to 35 days since a woman's last menstrual period (LMP).

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 05/05/2025, Allendale Investigational Review Board (30 Neck Road, Old Lyme, CT, 06371, United States of America; +1 (0)860 575 0092; erin.staab@allendaleirb.com), ref: Protocol #1001

2. Submitted 19/08/2025, Research Ethics Committee, Belisario Domínguez Specialty Hospital (Av. Tláhuac No. 4866, esq. Zacatlán. Col. San Lorenzo Texcoco. Alcaldía Iztapalapa,, Mexico City, 09790, Mexico; +1 (0)52 55 5850 0000 Ext. 1064; dgpcs.correspondencia@salud.cdmx.gob.mx), ref: N/A (number will be provided after approval)

Primary study design
Interventional

Study design
Multicenter interventional doubled-blinded randomized controlled trial

Study type(s)
Efficacy, Prevention, Safety, Treatment

Health condition(s) or problem(s) studied
Prevention or disruption of unwanted pregnancy in women up to 35 days LMP

Interventions
Arm 1: 60 mg (two 30 mg tablets) ulipristal acetate orally, followed 24 hours later by 800 mcg (four 200 mcg tablets) of misoprostol buccally.

Arm 2: 60 mg (two 30 mg tablets) ulipristal acetate orally, followed 24 hours later by four placebo tablets buccally.

Randomization is 1:1 and carried out in blocks of 8 for each study site using a computer program.

Intervention Type
Drug

Phase
Phase I/II

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

Primary outcome(s)
Proportion of study participants not pregnant at follow-up, as determined by urine pregnancy test and, for those with a positive urine test, ultrasound

Key secondary outcome(s)
1. Self-reported incidence of side effects (diarrhea, nausea/vomiting, cramps, fever, chills or other) after taking the study medications, as measured by an exit interview at follow-up.
2. Acceptability of the contragestive medications to participants, defined as the proportion of participants who report at follow-up that the medications were acceptable or highly acceptable.
3. Incidence of bleeding within five days after administering the study medications, defined as the proportion of participants who report at follow-up that they experienced any bleeding in the

first 5 days after taking the study medications.
4. Duration of bleeding in days following administration of the study medications, defined as the number of days that participants report experiencing bleeding after taking the study medications, as measured by an exit interview at follow-up.
5. Severity of bleeding following administration of study medications, defined as the proportion of participants who report that the bleeding they experienced was very severe, somewhat severe, or not severe at all, as measured by an exit interview at follow-up.

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Age 18-39 years
2. LMP ≤35 days, as verified by report of last menstrual period
3. Missed the EC window (had unprotected sex >5 days ago)
4. General good health
5. Does not want to be pregnant
6. History of regular monthly menstrual cycles (±3 days)
7. Willing and able to understand and sign consent forms
8. Willing to return for a follow-up visit
9. Willing to provide a blood draw at enrollment and urine sample at follow-up

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
39 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Known allergies or contraindications to either of the study drugs
2. Symptoms of or risk factors for ectopic pregnancy, including:
2.1. Unilateral pelvic pain or significant bilateral pelvic pain within the past week
2.2. Prior ectopic pregnancy

2.3. Prior permanent contraception or other tubal surgery
3. Current use of an IUD, contraceptive implant or injectable
4. History of renal or liver disease

Date of first enrolment
01/12/2026

Date of final enrolment
31/12/2027

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
Cuidado Integral de la Mujer, Gineclinic, S.C.
Barranca del Muerto 516
Los Alpes
Álvaro Obregón
Mexico City
Mexico
01010

Study participating centre
Centro Médico Mujer
Av. Baja California 111B
Roma Sur
Cuauhtémoc
Mexico City
Mexico
06760

Sponsor information

Organisation
Verge Research

Funder(s)

Funder type
Charity

Funder Name
David and Lucile Packard Foundation

Alternative Name(s)
David & Lucile Packard Foundation, The David and Lucile Packard Foundation, Packard Foundation, The Packard Foundation, The David & Lucile Packard Foundation, Packard, DLPF, PF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
Verge Research

Results and Publications

Individual participant data (IPD) sharing plan

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