ISRCTN97110708 https://doi.org/10.1186/ISRCTN97110708

How the body processes doses of hormone and NSAID drugs

Submission date
24/02/2026

Recruitment status
Recruiting

Registration date
30/03/2026

Overall study status
Ongoing

Last Edited
07/10/2026

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 study is investigating a new “on demand” birth control pill that combines a hormone with an NSAID. Hormones can disrupt ovulation (the process leading to the ovaries to produce an egg) when taken around the time of sex, but they don't work very well on their own for this purpose. NSAIDs may also help block ovulation and could make the hormone more effective. This study will look at how each drug works in the body, alone and together, when taken just before ovulation.

Who can participate?
Healthy female volunteers aged 18 to 40 years.

What does the study involve?
This study has two parts. In Part 1, people take part in a threeperiod, randomised crossover trial. This means each participant will receive three different onetime treatments, but in different orders. The order is randomly assigned by a secure computer system, and participants only find out which treatment they will get right before they take it. All treatments are given in the clinic by trained study staff.
The four possible treatments are:

A single 15 mg tablet of an NSAID.
A single 1.5 mg tablet of a hormone.
Both taken together as two separate tablets.
A single study tablet that combines both into one pill.

Each participant in Part 1 will receive three of these interventions in a sequence determined at random.
In Part 2, a smaller group of participants will take part in a pharmacokinetic assessment of the bilayer study tablet (the combined pill). This involves measuring how the body absorbs, distributes, and processes the medication after it is taken.

What are the possible benefits and risks of participating?
Benefits and risks not provided at time of registration

Where is the study run from?
Profamilia, Dominican Republic.

When is the study starting and how long is it expected to run for?
April 2026 to April 2027

Who is funding the study?
CIFF IP Co Limited, UK.

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
Pharmacodynamic and pharmacokinetic responses to a hormone and NSAID, administered individually and in combination

Acronym
POCP

Study objectives
Evaluate and compare the effect of a hormone and NSAID on ovarian function when administered in the advanced follicular phase individually and in combination

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/03/2026, PROFAMILIA Ethics Committee (Dominican Association for Family Welfare, Inc. 160 Socorro Sánchez Street, Gazcue, P.O. Box 1053, Santo Domingo, -, Dominican Republic; +1 809-689-0141; info@profamilia.org.do), ref: 2402074

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Evaluation of a hormone and NSAID on ovarian function in healthy female volunteers

Interventions
Current interventions as of 28/09/2026:

3-period, randomized, cross-over trial (Part 1), followed by a pharmacokinetics assessment of the a combined product in a subset of participants (Part 2)
Intervention 1: One-time oral dose of a single tablet of an NSAID (a non-steroidal anti-inflammatory drug) provided in the clinic by a trained study investigator.
Intervention 2: One-time oral dose of a single tablet of a hormone provided in the clinic by a trained study investigator.
Intervention 3: One-time oral dose of an NSAID and a hormone provided in the clinic by a trained study investigator.
Intervention 4: One-time oral dose of the single study tablet (combined product) provided in clinic by a trained study investigator.

Randomization
Enrolled and consented participants will be randomized to one of 6 treatment sequences in this three-period crossover trial. Each participant’s treatment sequence will be determined based on a randomly permuted block design generated using a validated software program. Treatment sequences will be concealed using a web-based interactive system, with each participant's treatment revealed immediately prior to dosing.

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Previous interventions:

3-period, randomized, cross-over trial (Part 1), followed by a pharmacokinetics assessment of the a combined product in a subset of participants (Part 2)
Intervention 1: One-time oral dose of a single tablet of an NSAID (a non-steroidal anti-inflammatory drug) 15mg provided in the clinic by a trained study investigator.
Intervention 2: One-time oral dose of a single tablet of a hormone 1.5mg provided in the clinic by a trained study investigator.
Intervention 3: One-time oral dose of an NSAID 15mg and a hormone 1.5mg provided in the clinic by a trained study investigator.
Intervention 4: One-time oral dose of the single study tablet (combined product) provided in clinic by a trained study investigator.

Randomization
Enrolled and consented participants will be randomized to one of 6 treatment sequences in this three-period crossover trial. Each participant’s treatment sequence will be determined based on a randomly permuted block design generated using a validated software program. Treatment sequences will be concealed using a web-based interactive system, with each participant's treatment revealed immediately prior to dosing.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Hormone, NSAID

Primary outcome(s)
1. Disrupted ovulation measured using transvaginal ultrasound (TVS), luteinizing hormone (LH) and progesterone via by serum blood tests at 1-6 days after treatment

Key secondary outcome(s)
1. Disrupted ovulation measured using LH surge onset, after LH surge onset but before LH peak, or at/after LH peak via serum blood tests at 1- 6 days after treatment

2. Pharmacokinetics of a hormone and NSAID measured using drug concentrations concentrations via plasma blood tests at 0.5, 1, 1.5, 2, 2.5, 4, 6, 8, 12, and Days 1-6 postdose

3. Effect of a hormone and NSAID on sex hormone binding globulin (SHBG) measured using SHBG concentrations via serum blood tests at pre-dose and Days 1-6 post-dose

4. Effect of a hormone and NSAID on cervical mucus measured using Cervical mucus score (CMS) via cervical mucus collection at pre-dose, and at 8 hours and Days 1-6 post-dose

5. Effect of a hormone and NSAID on the menstrual cycle and hormone levels measured using LH, estradiol, and progesterone via serum blood tests at beyond the 6 days after treatment

Completion date
30/04/2027

Eligibility

Key inclusion criteria
1. Is 18 to 40 years of age (inclusive)
2. Is in good general health based on results of physical examination, medical history and vital signs tests
3. Is able and willing to provide informed consent and follow all trial requirements
4. Has regular menstrual cycles (24-35 days)
5. Has ovulatory cycle during the screening
6. Has had tubal ligation
7. Has a body mass index of 18.0-35.0 (kg/m2)
8. Has hemoglobin ≥10.0 g/dl

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Recently (within the last 3 months) or currently pregnant
2. Is currently lactating
3. Has more than one risk factor for cardiovascular disease (such as smoking, diabetes, hypertension, and known dyslipidemias)
4. Has hypertension with systolic blood pressure ≥160 mmhg, and/or diastolic blood pressure ≥100 mmhg
5. Has hypertension with vascular disease
6. Has a history of coronary artery bypass graft (CABG) surgery
7. Currently has and/or has a history of acute deep vein thrombosis (DVT) and/or pulmonary embolism (PE) or a hereditary or acquired predisposition or elevated risk for venous thrombosis
8. Currently has or has a history of ATE (myocardial infarction, stroke, or peripheral arterial disease) or a hereditary or acquired predisposition or elevated risk for arterial thrombosis
9. Has a history of cerebrovascular bleeding, gastrointestinal bleeding, or other bleeding disorders
10. Has systemic lupus erythematosus
11. Has migraine with aura
12. Has unexplained vaginal bleeding
13. Has undiagnosed mass in the breast
14. Currently has and/or has a history of breast cancer
15. Currently has cervical cancer (including CIN 3)
16. Has known hypersensitivity to hormonal medications
17. Has known hypersensitivity to non-steroidal anti-inflammatory drugs(NSAIDS) (e.g., anaphylactoid reactions and serious skin reactions)
18. Has a history of asthma, nasal polyps, angioneurotic oedema or urticaria after taking aspirin or other NSAIDS
19. Has a history of recurrent peptic ulcer, perforation or gastrointestinal bleeding, related to previous NSAIDS therapy
20. Uses of any investigational or prohibited drugs per protocol
21. Has liver cirrhosis
22. Currently has and/or has a history of liver tumors (benign or malignant)
23. Knows of active liver disease
24. Knows of active renal disease
25. Plans to move to another location in the next 8 months that would interfere with trial participation
26. Has previously participated in this trial
27. Is currently participating in another clinical trial
28. Has any condition (social or medical) which in the opinion of the site investigator would make trial participation unsafe, would interfere with adherence to trial requirements or complicate data interpretation

Date of first enrolment

06/04/2026

Date of final enrolment
30/12/2026

Locations

Countries of recruitment
Dominican Republic

Sponsor information

Organisation
FHI 360

Funder(s)

Funder type

Funder Name
CIFF IP Co Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available