

# Mifepristone ovarian function study

ACTRN12605000698673

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Status	RECRUITING
Phase	Phase 3
Sponsor	FPA Health
Enrollment	40 participants

## Plain Language Summary

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This study is for women who are using Implanon (a small rod implanted under the skin of the arm that prevents pregnancy). A common problem with Implanon is irregular bleeding. This study is testing whether a medicine called mifepristone, with or without oestrogen, can help reduce unexpected bleeding while keeping Implanon working as a contraceptive. Participants will have ultrasound scans, cervical mucus checks, and blood tests over 4 weeks.

You may be eligible if:

- You are a woman between 18 and 45 years old
- You have been using Implanon for at least 3 months
- You are willing to have regular blood tests, vaginal ultrasounds, and cervical mucus collections over a 4-week period
- You are willing to use condoms for the entire study period

You may NOT be eligible if:

- You are pregnant
- You have had a heart attack, stroke, or blood clot in a vein
- You have high blood pressure (above 160/95)
- You have severe liver or kidney disease
- You have a history of focal migraines
- You have or have had breast cancer or genital cancer
- You have a known sensitivity to ethinyl oestradiol or lactose
- You are taking phenytoin, carbamazepine, or phenobarbitol
- You are breastfeeding

Talk to your doctor about whether this trial might be right for you.

## Key Eligibility Criteria

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### Inclusion (1)

- Implanon users, who have been using Implanon for three months. Women who are willing to participate in a research investigation of new approaches to the therapy of breakthrough bleeding. Women who are prepared to have regular venepuncture, vaginal ultrasound and cervical mucus collection over a period of four weeks.

### Exclusion (1)

- Pregnancy. Women who have currently or previously had Heart attack or stroke Blood clot in a vein High blood pressure Severe liver or kidney disease Blood pressure >160mm systolic or >95mm diastolic Focal migraine Breast cancer or any genital cancer Women with known sensitivity to ethinyl oestradiol, or lactose Women taking phenytoin, carbamazepine or phenobarbitol or Women who are lactating.

## Locations (1 total)

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Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12605000698673>

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