

Palmitoylethanolamide and polydatin effect on pain and dysmenorrhea in women scheduled for laparoscopic treatment of possible endometriosis: a double blind randomised controlled trial.

ACTRN12620001311943

Status	RECRUITING
Phase	Phase 3
Sponsor	The University of Melbourne
Enrollment	260 participants

Plain Language Summary

Endometriosis is a condition where tissue similar to the lining of the uterus grows outside it, causing pelvic pain, painful periods, and sometimes difficulty conceiving. Effective medical treatments are limited, and many options come with unwanted side effects. Researchers are exploring natural food supplements as a gentler alternative.

This trial is testing a combination of two food supplements — Palmitoylethanolamide (PEA) and Polydatin (PLD) — in women who are already scheduled for keyhole surgery to investigate or treat endometriosis. PEA has anti-inflammatory properties, and PLD has antioxidant and pain-relieving effects. Small earlier studies suggested they may help with endometriosis-related pain, but larger trials are needed.

Women aged 18–45 who are booked for laparoscopic surgery for possible endometriosis and willing to use contraception during the study period may be eligible. Participants will take either the PEA/PLD supplement or a placebo (a dummy pill) for 8 weeks before their surgery. You will complete pain and quality-of-life surveys at the start, before surgery, and 6 months later. Joining this study will not change your planned surgical care.

Key Eligibility Criteria

Inclusion (3)

- Women aged 18 – 45 with pelvic pain scheduled for laparoscopic treatment of possible endometriosis. Both women with and without previous evidence of endometriosis on ultrasound or previous surgery are eligible
- Women who agree to use any type of contraception and avoid conceiving during the 8-week treatment phase.
- English speakers

Exclusion (5)

- Pregnancy or actively trying to conceive
- Breastfeeding
- Previous hysterectomy
- Suspected malignancy
- Inability to provide informed consent

Locations (11 total)

The Royal Women's Hospital - Parkville, VIC, Australia
Mercy Hospital for Women - Heidelberg, VIC, Australia
Frances Perry House - Parkville, VIC, Australia
... and 8 more locations

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12620001311943>

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