

# Fractional CO2 laser for postmenopausal vaginal symptoms - a follow-up study

ACTRN12621000361808

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<b>Status</b>	RECRUITING
<b>Sponsor</b>	GRACE Unit - School of Women's and Children's Health, UNSW Sydney, Australia
<b>Enrollment</b>	30 participants

## Plain Language Summary

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After menopause, declining oestrogen levels can cause vaginal dryness, discomfort during sex, and urinary symptoms — a cluster of issues sometimes called genitourinary syndrome of menopause. Fractional CO2 laser treatment is a relatively new option that uses gentle laser pulses to stimulate the vaginal lining and encourage its renewal. This follow-up study is offering treatment to women who participated in an earlier double-blind randomised trial (where neither they nor the doctors knew who received real laser treatment and who received a sham), now that the trial results are complete.

Participants from both the laser group and the sham (placebo) group from the original trial are being offered the opportunity to receive one full course of laser treatment — three sessions, four weeks apart. Before each session, they complete questionnaires assessing their symptom severity. Adverse events are reported at every visit.

This follow-up study will provide additional long-term data on whether the laser treatment is effective, and also helps explore the extent of any placebo effect observed in the original trial. It offers all previous trial participants the potential benefit of the treatment while contributing valuable scientific knowledge.

## Key Eligibility Criteria

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### Inclusion (6)

- Symptomatic women with 1 AND 2 or 3
  - Previously participated in the double blind placebo-controlled randomised trial of fractional CO2 laser
  - AND
  - Post-menopausal women who have not had a menstrual period for at least 12 months (with an intact uterus) and/or have vulvovaginal symptoms substantial enough for them to present to their health care provider due to symptoms
  - OR
- ... and 1 more (see full listing online)

### Exclusion (6)

- Current urinary tract infection.
  - Active genital infections.
  - Current genital herpes infection.
  - Pelvic organ prolapse (most substantial prolapse) POPQ system stage 2.
  - Previous vaginal prolapse surgery where there is mesh repair in the pelvis.
- ... and 1 more (see full listing online)

## Locations (1 total)

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Royal Hospital for Women - Randwick, NSW, Australia

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12621000361808>

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