

Phyto-Soya Vaginal Gel Study

ACTRN12606000020583

Status	RECRUITING
Phase	Phase 2
Sponsor	Arkopharma Australia
Enrollment	60 participants

Plain Language Summary

This study is testing a vaginal gel containing phytoestrogens (plant-based oestrogen-like compounds from soy) for postmenopausal women experiencing vaginal dryness, itching, or painful sex. After menopause, falling oestrogen levels can cause the vaginal tissue to become dry and thin. This study tests whether this gel can relieve these symptoms as an alternative to hormonal treatments.

You may be eligible if:

- You are a postmenopausal woman aged 40 or older
- You experience at least one of the following: vaginal dryness, vaginal itching, painful sexual intercourse, or elevated vaginal pH above 5 at screening

You may NOT be eligible if:

- You have used systemic or topical oestrogens within the past 8 weeks
- You have used effective menopausal herbal remedies within the past 4 weeks
- You have vulval dystrophy (a skin condition of the vulva)
- You currently have a vaginal infection or urinary tract infection
- You have had vaginal surgery in the past 12 months

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

Key Eligibility Criteria

Inclusion (1)

- Postmenopausal woman and one of the following: Vaginal dryness, vaginal itching, Painful sexual intercourse, Vaginal pH >5 at screening.

Exclusion (1)

- Systemic or topical oestrogens within 8 weeks. effective menopausal herbals within 4 weeks, Vulval dystrophy, Current vaginal or urinary tract infection, Any vaginal surgery within 12 months.

Locations (1 total)

Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12606000020583>

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