

Is amitriptyline cream effective in the management of vestibulodynia - a condition which refers to pain at the opening of the vagina?

ACTRN12612000655842

Status	RECRUITING
Phase	Phase 3
Sponsor	Dr Ross Pagano
Enrollment	50 participants

Plain Language Summary

This study tests whether a cream containing amitriptyline (a medication usually used for nerve pain and depression) can relieve pain at the opening of the vagina, a condition called vestibulodynia. Women with this condition feel pain whenever pressure is applied to that area. The cream is applied directly to the skin and may reduce pain signals in the area.

You may be eligible if:

- You are a woman aged 18 or older
- You have been diagnosed with provoked localized vestibulodynia (pain at the vaginal opening when touched)

You may NOT be eligible if:

- You have already had surgery to remove the painful tissue (vestibulectomy)
- You have been treated with amitriptyline cream before
- You are currently pregnant
- You have an active vaginal or pelvic infection or yeast infection at the time of enrollment
- You are unable to read or communicate in English

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

Key Eligibility Criteria

Inclusion (1)

- Women aged 18 and older presenting with provoked localised vestibulodynia classified according to 2003 International Society for the Study of Vulvar Disease classification will be eligible for inclusion. Primary vaginismus will be excluded in all participants after physical examination.

Exclusion (2)

- Patients who have undergone a vestibulectomy, been previously treated with amitriptyline cream or are currently pregnant will be excluded. If a patient is found to have active vaginal or pelvic infection or vaginal candidiasis then treatment must be given prior to enrolment in the study.
- Patients who cannot speak English or give adequate consent will also be excluded.

Locations (1 total)

Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12612000655842>

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