

Pilot study of Anal Neoplasia Treatment in people with HIV Evaluation and monitoring (short title: PANTHER)

ACTRN12624000154505

Status	RECRUITING
Sponsor	University of New South Wales Sydney, NSW, Australia
Enrollment	100 participants

Plain Language Summary

People living with HIV have a significantly higher risk of developing anal high-grade squamous intraepithelial lesions (HSIL) — a type of precancerous tissue change in the anal canal caused by certain strains of HPV (human papillomavirus). Without treatment, HSIL can progress to anal cancer over time.

The PANTHER study tests whether electrocautery — a procedure that uses heat to destroy abnormal tissue — is an effective and well-tolerated treatment for persistent HSIL in people with HIV. Participants will be followed up closely after treatment to see whether the abnormal cells clear, and to check for side effects.

You may be eligible if you are 18 or older, living with HIV, and have been diagnosed with persistent HSIL on two or more occasions at a specialist clinic. People who have had other HSIL treatment within the past 3 months, have a pacemaker, are pregnant, or have extensive perianal disease may not be eligible.

Key Eligibility Criteria

Inclusion (7)

- Aged 18 years or older
 - Documented HIV positive
 - Current patient of the Dysplasia and Anal Cancer Services (DACs) clinic under active follow-up
 - Histologically established persistent intra-anal HSIL of 4 or fewer octants diagnosed on 2 or more occasions, OR intra-anal HSIL considered by study doctor to be eligible for treatment
 - Willing to not undergo any other anal HSIL therapeutic interventions while taking part in the study. Treatment for anal conditions other than HSIL (such as dermatological abnormalities) may be allowed with the permission of the study doctor.
- ... and 2 more (see full listing online)

Exclusion (13)

- History of any other HSIL treatment within 3 months prior to the Baseline visit
 - Any perianal HSIL diagnosed, alone or in conjunction with intra-anal HSIL
 - Substantial quantity of anal verge HSIL subject to clinicians' discretion
 - Intra-anal exophytic low-grade lesions, the extent of which compromises the ability to deliver effective electrocautery
 - Any anal or rectal pathology such as ulcer, fistula, stricture, or stenosis that, in the clinician's assessment, is likely to adversely affect the efficacy of treatment
- ... and 8 more (see full listing online)

Locations (1 total)

St Vincent's Hospital (Darlinghurst) - Darlinghurst, NSW, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12624000154505>

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