

Interim results from a Pilot trial of Anal Neoplasia Treatment in people living with HIV in Sydney, Australia (the PANTHER study)

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Background: People living with HIV (PLHIV) have up to 100-fold higher incidence of anal cancer than the general population. A randomised trial in PLHIV with anal high grade squamous lesions (HSIL) showed that treating anal cancer precursors, mostly with electrocautery, decreased cancer incidence by 57%. We are evaluating the effectiveness, acceptability, and tolerability of electrocautery treatment in PLHIV with persistent intra-anal HSIL.

Methods: A single-site single-arm prospective pilot trial of electrocautery treatment of persistent anal HSIL in PLHIV in Sydney is underway. To be eligible, a prior diagnosis of anal HSIL of < 4 octants of disease is required. Participants receive up to 5 treatments, at least 12 weeks apart, and are followed for 12 months after final treatment. Clearance (total and partial) of index lesions at the 12-month post-treatment visit and adverse events (AEs) of treatment are measured.

Results: A total of 76 people screened were eligible and 53 consented to join the study. All 53 participants reported male sex at birth, and being gay/homosexual. The median age was 62 years (range 35-76), 43 (81.1%) were born in Australia and one participant identified as Aboriginal or Torres Strait Islander. Forty (75.5%) have received the first treatment and a total of 82 treatments have been delivered. Of the 19 (47.5%) who have completed treatment, the average number of treatments required was two. Five serious AEs (all study-unrelated) and 282 AEs have been reported. The most common AEs are anal discomfort (71, 25%) pain (64, 22.7%) and bleeding (65, 23.0%).

Conclusion: This is the first study in Australia assessing the effectiveness of electrocautery treatment of anal HSIL. Treatment has been well tolerated thus far. Most participants have only required 2 treatments to clear their HSIL, however this may over-estimate the proportion who will require short duration therapy. Follow up is continuing.

Disclosure of interest: N/A