

# Feasibility Study of Ocular Surface Squamous Neoplasia Surgical Excision in People Living With HIV in Sub-Saharan Africa

NCT04704648

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<b>Status</b>	RECRUITING
<b>Phase</b>	Not Applicable
<b>Sponsor</b>	AIDS Malignancy Consortium
<b>Enrollment</b>	84 participants

## Key Eligibility Criteria

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### Inclusion (8)

- Participants with suspected unilateral, non-invasive OSSN lesions that the AMC-certified ophthalmologist determines can be resected with 3 mm clinical margins, sparing involvement of the superior and inferior fornices as well as 6 clock hours of the corneal scleral limbus. This assessment must be carried out within 4 weeks before surgery.
- HIV positive. Documentation of HIV-1 infection by means of any one of the following:
- Documentation of receipt of ART by a licensed health care provider (Documentation may be a record of an ART prescription in the participant's medical record, a written prescription in the name of the participant for ART, or pill bottles for ART with a label showing the participant's name. Antiretroviral drug regimens used for pre-exposure prophylaxis (PrEP) may not satisfy this requirement.;
- HIV-1 RNA detection by a licensed HIV-1 RNA assay demonstrating  $>1000$  RNA copies/mL confirmed by a licensed screening antibody and/or HIV antibody/antigen combination assay;
- Any licensed HIV screening antibody and/or HIV antibody/antigen combination assay confirmed by a second licensed HIV assay such as a HIV-1 Western blot confirmation or HIV rapid multispot antibody differentiation assay.

... and 3 more (see full listing online)

### Exclusion (3)

- Participants who are receiving any other investigational agents within 30 days before enrollment for surgery, except for investigational ART regimens, which will be permitted.
- Participants with known history of ocular surface lesions including OSSN, other ocular neoplasm, pterygia, or limbal vernal keratoconjunctivitis.
- Uncontrolled intercurrent illness within 4 weeks before enrollment, including but not limited to ongoing or active infection, or psychiatric illness/social situations that would limit compliance with study requirements.

## Locations (1 total)

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Uganda Cancer Institute, Kampala, Uganda