ISRCTN12095550 https://doi.org/10.1186/ISRCTN12095550

Screening study for anal pre-cancer in HIV positive men who has sex with men in Sweden.

Submission date
14/10/2025

Recruitment status
No longer recruiting

Registration date
16/10/2025

Overall study status
Completed

Last Edited
25/11/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Anal cancer is becoming more common among men who have sex with men (MSM) who are living with HIV. This is often linked to long-term infection with the human papillomavirus (HPV), which can cause changes in the cells of the anus. The current best method to detect these changes is called high-resolution anoscopy (HRA), but it's expensive and not widely available. This study is looking at whether a simpler method—called flexible endoscopy—could be a good alternative for screening. Researchers are comparing how well flexible endoscopy works compared to other tests like HPV testing and cell analysis (cytology).

Who can participate?
Men who have sex with men (MSM) and transgender people who are living with HIV can take part in the study.

What does the study involve?
Participants will be asked to provide some basic information about their health and background. They will have a sample taken from the anal area using a soft brush, which will be tested for HPV and cell changes. They will also have a flexible endoscopy, which is a visual examination of the anal canal using a thin, bendable tube. If any abnormal cell changes are found, participants will be informed and referred for further treatment. They will also be followed up as part of a monitoring program.

What are the possible benefits and risks of participating?
Taking part in the study may help detect early signs of anal cancer, which can lead to timely treatment. However, the procedures may cause some discomfort. Because the study involves sensitive topics like sexual health, some participants may feel anxious, embarrassed, or concerned—especially while waiting for results. The researchers understand this and aim to treat all participants with respect and care.

Where is the study run from?
The sample collection is done at Södersjukhuset, and the flexible endoscopy is carried out at Ersta Hospital in Sweden. The research is being led by Ersta Diakoni.

When is the study starting and how long is it expected to run for?
The study began in January 2022 and is expected to finish in 2024.

Who is funding the study?
The study is funded by the Regional Cancer Center Stockholm-Gotland, the Sjöberg Foundation, and the Swedish Physicians Against AIDS Research Foundation.

Who is the main contact?
Prof Peter Thelin Schmidt, Peter.Thelin.Schmidt@medsci.uu.se

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Peter Thelin Schmidt

Contact details
Akademiska sjukhuset
Uppsala
Sweden
751 85
+46 725449961
Peter.Thelin.Schmidt@medsci.uu.se

Additional identifiers

Study information

Scientific Title
Pilot screening study for anal squamous intraepithelial lesions (ASIL) in HIV-positive MSM in Sweden: comparison of anal cytology and flexible endoscopy

Acronym
SAP-study

Study objectives
The overall goal is to evaluate flexible endoscopy as a method for screening and treatment of anal precancer and compare it against anal cytology including HPV testing.
The highest risk of developing anal cancer is found in HIV-positive men who have sex with men, which is why, in a first step, we want to investigate the benefit of screening in this group.
We want to compare the diagnostic value of anal cytology, anal HPV test and flexible endoscopy.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/06/2021, Göteborg avdelning 1 medicin (Södra allégatan 8., Göteborg, 41301, Sweden; +46 10-475 08 00; registrator@etikprovning.se), ref: Dnr 2021-02895

Primary study design
Interventional

Study design
Single center prospective interventional non randomized

Study type(s)
Prevention

Health condition(s) or problem(s) studied
ASIL, Anal squamous intraepithelial lesions

Interventions
As this is a screening study, all participants undergo the same sampling and endoscopic examination procedures. At Södersjukhuset, anal samples for HPV PCR and cytology are collected using a Cytobrush® swab in ThinPrep® PreservCyt® 20 mL solution. Samples for Chlamydia trachomatis and Neisseria gonorrhoeae are obtained using the Cobas® PCR dual swab kit.
At Ersta Hospital, participants undergo high-resolution flexible endoscopy of the anal canal (HR-FEA). If anal dysplasia is suspected, participants are scheduled for endoscopic resection of the lesion. Single dysplastic lesions—classified as HSIL (High-Grade Squamous Intraepithelial Lesions) or LSIL (Low-Grade Squamous Intraepithelial Lesions)—are followed up after 6 months. Cases with multifocal lesions are re-evaluated every 2–3 months until clearance. Endoscopic surveillance is performed biannually during the first year, followed by annual follow-ups if no recurrence is observed. In cases of relapse or newly detected anal squamous intraepithelial lesions (ASIL), participants are reassessed after 6 months to monitor disease progression. Baseline is defined following the initial resection.

Intervention Type
Procedure/Surgery

Primary outcome(s)
At baseline and each follow up:
1. The outcome of histopathological evaluation is into three groups:
1.1. HSIL (including Indefinite HSIL/LSIL),
1.2. LSIL, and
1.3. No Dysplasia (combining “no dysplasia in resected tissue” and “no lesions at index endoscopy”).
2. The outcome of HPV PCR is grouped into:
2.1. High-risk (Hr) HPV (including types 16 and 18),
2.2. Low-risk (Lr) HPV, and
2.3. No HPV (including cases with insufficient material).
3. The outcome of cytology evaluation is categorized as:
3.1. ASC-H, HSIL, Indefinite HSIL/LSIL,
3.2. ASCUS/LSIL, and
3.3. Benign (including Condyloma and insufficient material).

Key secondary outcome(s)
1. Pain is measured using visual analogue score (VAS) and Numerical Rating Scale (NRS) after anal sampling and endoscopy, in an anonymous questionnaire. NRS is used after endoscopy and

documented.
2. The acceptability of flexible endoscopy of the anal canal and cytology and HPV testing measured using a questionnaire at each visit.

Completion date
01/10/2025

Eligibility

Key inclusion criteria
MSM (Men who have sex with men) and transgender persons living with HIV, aged 18 years or older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
Male

Total final enrolment
304

Key exclusion criteria
1. Rectal amputees
2. Do not speak Swedish or English

Date of first enrolment
21/01/2022

Date of final enrolment
20/05/2024

Locations

Countries of recruitment
Sweden

Study participating centre
Ersta hospital
Folkungagatan 125
Stockholm
Sweden
11630

Study participating centre
Södersjukhuset
Sjukhusbacken 10
Stockholm
Sweden
118 61

Sponsor information

Organisation
Ersta Diakoni

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Regional Cancer Center Stockholm-Gotland

Funder Name
The Sjöberg Foundation

Funder Name
Swedish physicians against AIDS research foundation

Results and Publications

Individual participant data (IPD) sharing plan

All study data will be compiled in a secure database at Ersta Hospital, accessible only to study personnel. Results from cytology, HPV tests, and endoscopy will be stored in the TakeCare medical record system.
Case Report Forms (CRFs) and questionnaires will be stored at both Infection Clinic 2/Venhälsan, Södersjukhuset AB and the research unit at Ersta Hospital. Each participant will receive a unique study ID. The code key and original documents will be kept at Venhälsan, with copies sent to Ersta.
Cytology and HPV results may be stored in a password-protected Excel file at Venhälsan. At Ersta, CRFs and questionnaires will be stored securely, and all data entered into the database will be de-identified.
Data protection officers and data controllers are in place at both Södersjukhuset and Ersta Hospital.

The datasets can be available upon request from: Peter.borch-johnsen@erstadiakoni.se

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	30/11/2021	16/10/2025	No	Yes