Screening for cell changes in the anal canal – comparison between anal cytology and flexible endoscopy.

Request for participation
You are being asked to participate in a research study to detect cell changes in the anal canal mucosa at an early stage. Cell sampling in the anal canal, so-called anal cytology, will be compared with an examination of the anal canal with an endoscope. This means that, with the help of a flexible instrument (endoscope), the anal canal is examined and tested (screened) for cell changes.

The study is being carried out as a collaboration between the Infektionsmottagning 2/Venhälsan at Södersjukhuset and the Endoskopienheten at Ersta Sjukhus. The information here describes what the study involves; the study has been reviewed and approved by the Ethics Review Board.

Background and aim
Cell changes in the anal canal, AIN (Anal Intraepithelial Neoplasia) can be a precursor to anal cancer. Anal cancer is a relatively uncommon form of cancer in Sweden, although the disease is more common among some groups. Cell changes are caused by HPV virus (Human Papillomavirus), which is a very common virus that is sexually transmitted . HIV-positive men who have sex with men have a higher risk of developing anal cancer. There is currently no method in Sweden to test (screen) for anal cell changes and detect them early when they are easy to treat. Cell changes do not usually cause any symptoms and it is difficult to examine the anal mucosa in a standardised way. The aim of this study is to compare taking cell samples in the anal canal (anal cytology) with flexible endoscopy, as methods for screening.
Data on previous infections with rectal chlamydia and gonorrhea will be collected to investigate whether there is a link with possible cell changes. A rectal sample for chlamydia and gonorrhea will also be taken to investigate whether a concomitant infection may affect the outcome of cell sampling.

How will the study be carried out?
During a planned visit to the Infektionsmottagning 2/Venhälsan at Södersjukhuset, a cell sample will be taken from the anal mucosa. The cell sampling is carried out in a standardised way with a small brush (20 mm long, 5mm wide) which captures cells from the anal mucosa. The sample is then sent to the laboratory for analysis. Then a chlamydia and gonorrhea sample will be taken with a thin sampling stick. The cell samplings take less than a minute. You will later be given an appointment at Ersta Hospital for an endoscopic examination. This is performed with a flexible instrument (an endoscope) that is about 1 cm in diameter and which is inserted about 5-7 cm into the anal canal. An anaesthetic cream is applied both outside and inside the anal canal to reduce discomfort. In this method, we can visualise the whole anal canal with a camera. During the examination, pictures are taken of the skin and mucosa that are saved in your medical record.

The visit normally takes about 30 minutes and the actual examination takes 5-10 minutes.

The cell sample taken at the Infektionsmottagning 2/Venhälsan at Södersjukhuset will be compared with the result from the endoscopic examination. The results of the cell sample and the endoscopy examination will then be compared. If anything is discovered with any of the methods, you will be offered a follow-up examination /sampling of the cells and, if necessary, treatment to remove the cell changes.

You will also be asked to fill out a questionnaire about how you experienced the cell sampling and the endoscopic examination.

What are the risks?
Discomfort may be experienced during the cell sampling but this often passes quite quickly. Discomfort may also be experienced during the endoscopic examination at Ersta Hospital. Always contact your study doctor or nurse if you experience any problems afterwards.

Are there any advantages?
The study involves screening for cell changes in the anal mucosa, a method that is not yet routine in Swedish healthcare. The advantage is that a possible cell change can be detected at an early stage and then be removed before it develops into cancer.

Storage of samples in a biobank
The samples are stored routinely in a biobank supervised by a pathologist. The samples are managed according to the Swedish Biobanks in Medical Care Act (2002:297).

Data management and confidentiality?
During the study we will collect and register information about you. The data that is collected during the study is stored in a secure database and all information on paper is stored in a locked space. Your results will be managed so that no unauthorised person can access them. The results from the study will be presented scientifically at group level. It will not be possible to trace any information to you. Ersta Sjukhus has responsibility for your personal information and all data collected will be managed according to the General Data Protection Regulation (GDPR 2016/679). According to the EU's General Data Protection Regulation you have the right to access all information about you that is being used, without cost. If you are not satisfied with how your personal information is being managed you have the right to make a complaint to the Swedish Authority for Privacy Protection, which is a supervisory authority.

How will I receive information about the result?
You will be given your results by the respective hospital units. The results from the study are expected to be completed during 2023 and will be published scientifically.

Insurance and compensation
You will not be given any payment or other compensation for your participation in this study. Patient Insurance (The Patient Injury Act) applies in this study, in the same way as with all other treatment within the healthcare services.

Voluntary participation
Participation is voluntary and if you decline to participate or stop participating, this will not affect your current care, nor your care in the future. You can withdraw your consent at any time and stop participating without further explanation. If you do choose to end your participation, the data that has already been collected will be used in the study evaluation, but no further information about you will be registered. Please contact those responsible for the study if you decide to leave the study.

Patient number: _____
To be filled in by the research nurse

Persons responsible for the study:
Ersta Sjukhus, Endoskopienheten:

Peter Borch-Johnsen, Specialist nurse, Endoskopienheten. Tel: 0790–620 939.
Peter Thelin Schmidt, Consultant and project leader for the study. Tel: 08-714 64 35.
Ersta Sjukhus, Endoskopienheten, Fjällgatan 44, 116 28 Stockholm.

If you would like to access your information, you can contact Ersta Diakoni's Data Protection Officer, contact person Andrea Hemming dataskyddsombudet@erstadiakoni.se. Tel 08-714 50 65
Adress:Dataskyddsombudet Box 4619 116 91 Stockholm.
Remember to never send any personal details via e-mail.

Södersjukhuset, Infektionsmottagning 2/Venhälsan:
Finn Filén, Consultant. Tel reception: 08-1236 2500, Södersjukhuset's switchboard 08-1236 1000.
Elisabet Storgärd, Ronnie Ask, Research nurses. Tel direct: 08-1236 2696, reception: 08-1236 2500. Infektionsmottagning 2/Venhälsan, Södersjukhuset, Sjukhusbacken 14, 11 883 Stockholm.

I have received verbal and written information about the study and I have had the opportunity to ask questions. I agree to participate in the research study, that my participation is voluntary and I can stop participating at any time without explanation. I give permission for those responsible for the study to access my medical records for details that are relevant to the study.

_____	_____	_____
Date	Patient's signature	Print name

This original document will be saved at the research unit at the Infektionsmottagning 2/Venhälsan, Södersjukhuset and a copy will be saved at the research unit at Ersta Sjukhus. A copy is given to the patient.

_____	_____	_____
Date	Signature of responsible doctor/nurse/assistant nurse	Print name