PrEP-OPT study

A study to optimize PrEP services for men and transgender people who have sex with men (MSM)

Objectives of the study and ethical clearance

This research (the PrEP-OPT study) is being conducted to optimize and improve services and support for PrEP users at Venhälsan/Södersjukhuset. By investigating the occurrence of sexually transmitted infections (STIs) (syphilis, gonorrhea, chlamydia and also monkeypox) and how common or rare it is with kidney function complications when using PrEP, we seek to simplify our monitoring and prescription practices to improve quality if care and focus our resources where they are most needed.

The study is conducted at the Infectious Disease Clinic/Venhälsan, Södersjukhuset AB which is run by Region Stockholm, and it has been reviewed and approved by the Swedish Ethics Review Authority (dnr 2022-02235-01/2022-04503-02).

Venhälsan’s PrEP program today

Since October 2018, PrEP has been offered at Venhälsan for preventive purposes to people with an increased risk of HIV infection. At PrEP initiation and at the annual visit, everyone fills in a questionnaire ("MSM risk index") about sexual risk behavior (number of partners, type of unprotected sex, previous STIs, drug use, and any previous post-exposure prophylaxis against HIV (PEP)) in order to do a needs assessment before PrEP prescription is possible.

At the start of PrEP, we also ask about general health status, medications, sexual orientation, weight, height and previous vaccinations. Blood samples (antibody tests for HIV, syphilis, hepatitis B and C, kidney function (creatinine), swabs (pharyngeal and rectal chlamydia and gonorrhea) and urine samples (chlamydia and gonorrhea, creatinine) are also taken to assess whether it is safe to start PrEP and if any ongoing STIs need to be treated. The same tests are repeated at each return visit to check that PrEP is working and is safe to continue. This information is documented in Venhälsan's protected patient records.

Why is more research needed?

No scientific evaluation has been made of Venhälsan's PrEP program, even though we serve the largest number of PrEP patients in Sweden (approximately 1,700). An in-depth analysis of the data that is already routinely collected at all PrEP visits can lead to improvements and simplifications of PrEP services, not only at Venhälsan but for PrEP programs in general. If it becomes easier to identify people who run an increased risk of kidney damage, STIs, or who need more professional support to promote mental well-being, we can offer better and more timely services for those in need and simplify the follow-up for others. This would increase patient safety, quality of care and accessibility to PrEP, with the overall goal of optimizing well-being among PrEP users.

For some time, the monkeypox virus (Monkeypox) has been spreading in a new way in Europe, so far mainly via sexual contacts among men who have sex with men (MSM). Screening and vaccination for monkeypox may become part of future routine care for MSM in Sweden, and it is therefore of great importance to quickly analyze the occurrence of asymptomatic infection (i.e. carrier of the monkeypox virus without symptoms) and immunity at group level to understand the risk of transmission, immunity levels and future need for monkeypox vaccine, making sure that MSM using PrEP can benefit from the results as quickly as possible.

How is the study conducted?

During a PrEP visit, you will be asked if we can use your medical record data for research purposes to improve Venhälsan's program. When handling and storing your data in the study, your social security number will be replaced with a code ("pseudonymized"). The code key that connects the special code to you personally is kept by your healthcare provider and only personnel within the study have access to it.

The information we would like to use is your age, gender identity, height, weight, number of visits to Venhälsan since the first PrEP visit, medicines you have used since starting PrEP, results of tests for STIs and kidney function, use of drugs and alcohol that you have stated, MSM- risk index (see above), previous and current illnesses, as well as possible side effects of PrEP. You will also be asked if you have had monkeypox, been

vaccinated against monkeypox and if you know if you were vaccinated for smallpox earlier in life (e.g. childhood). If or when you stop PrEP, you also give permission for your de-identified (pseudonymized) information to be used to analyze which groups of PrEP users continue for different lengths of time.

All the data and test results that we wish to analyze are already collected on all PrEP users, except for the screening for monkeypox, which is not yet part of the PreP program's routine service but involves one extra urine sample and swab from the throat, rectum, while you already swab for other STIs. When blood tests for HIV and syphilis are taken, an extra sample will also be collected (approx. 7-15 ml of blood) for later analysis of immunity against monkeypox at group level, i.e. these results are not disclosed to individuals.

For those individuals who have symptoms/suspected ongoing infection for monkeypox, we will of course offer testing and let you know the test results as quickly as possible according to standard guidelines.

What are the risks and benefits?

As the data is collected and pseudonymized before data analysis and never leaves the clinic, we do not foresee any risks for you. The results can be rapidly implemented and lead to improvements and simplifications in PrEP care for all PrEP users (regardless of participation in the study).

Biobank storage of samples

All samples taken in healthcare are routinely stored in the hospital's biobank. The samples are handled in accordance with the Act on Biobanks in Health Care (2002:297). Samples for monkeypox will be frozen and stored in a biobank at Södersjukhuset AB/Folkhälsomyndigheten for later analysis of virus presence and immunity to the virus at group level.

Data management and confidentiality

During the study, you provide us with information that is pseudonymized, i.e. the information cannot be linked to your identity by any unauthorized personnel. The collected data is stored in a secure database and all paper materials are kept in a locked storage room. All data is analyzed pseudonymously at group level with not possibility of being traced back to you by anyone other than the staff responsible for the research. The study results are presented at group level only.

Södersjukhuset AB is responsible for your personal data. All collected data is processed in accordance with the Data Protection Regulation (GDPR 2016/679). You have the right to change incorrect

information, delete information, and the right to limit your personal data. According to the EU's data protection regulation, you also have the right to access all information about you free of charge.

If you are dissatisfied with the way your personal data is processed, you can complain to the Swedish Data Protection Authority, which can also provide more information about your rights www.imy.se/

If you have questions about Södersjukhuset's handling of personal data or about your own personal data, you can contact Södersjukhuset's data protection officer, who also gives advice on your rights www.sodersjukhuset.se/om-sos/behandling-av-personuppgifter-vid-sodersjukhuset www.1177.se/Stockholm/hitta-vard/kontaktkort/Journalservice-Sodersjukhuset-AB, www.1177.se/Stockholm/sa-fungerar-varden/sa-skyddas-och-hanteras-dina-uppgifter/dataskyddsombud/

Any general questions can also be asked by calling the hospital's switchboard: 08-616 1000 or email gdpr.sodersjukhuset@regionsstockholm.se. Remember to never to send personal data by e-mail.

How do I get information about results?

The first study results are expected to be ready in 2023 and will be published scientifically and via Venhälsan's own channels in 2023/2024 in order to be easily available for all patients.

Insurance and compensation

You will not receive any payment or compensation for your participation in this study. Patient insurance (Patient Damages Act) applies in the study, similar to all other healthcare in Sweden.

Participation is voluntary

Participation is voluntary and if you decline to participate or want to discontinue, it will not affect your care, neither today nor in the future. You can withdraw your consent at any time and end your participation without further explanation by contacting those responsible for the study (see below). If you choose to cancel your

participation, already collected pseudonymized data will be used in the results but no further information will be recorded about you. You can also request all the information you have contributed to be deleted completely from the study, including after the end of the data collection.

Those responsible for the study are:

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