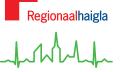




TERVISEKASSA∯







INVITATION

We invite you to participate in a study of early detection of prostate cancer. The aim of the study is to assess the feasibility of conducting a screening program in Estonia that considers men's individual risk of developing prostate cancer. Participation is voluntary and free of charge.

You have received this invitation because you are a man aged 50-69 (born between 1955-1974), residing in Tallinn or Tartu and to our knowledge you have not had a PSA (prostate specific antigen) test within 12 months. We invite 12 000 men to participate in this study.

As a first step to participate in the study, we ask you to give a blood sample for PSA measurement.

HOW TO MAKE AN APPOINTMENT FOR A BLOOD TEST

You can make an appointment to give a blood sample via online booking system: env.synlab.ee or by calling the laboratory at 17123.

For online booking you will need to identify yourself using your ID-card, Mobile-ID or Smart-ID. For booking by phone, you will need your personal identification number. You can choose the most convenient location for you to give a blood sample. In addition, you will be asked to provide consent to participate in the study and for the processing of your personal data.

When going to the blood sampling cabinet, please bring along a valid identification (ID-card, passport etc). It is recommended to refrain from ejaculation and bicycle riding 48 hours prior to the blood test, as these activities may affect the PSA value.

You can give a blood sample for PSA test until December 31, 2024.

WHAT HAPPENS NEXT?

The laboratory will personally inform you of the PSA test result using your preferred method of contact (SMS, e-mail, encrypted e-mail, regular mail). You can also check your test result in the Health Information System (www.terviseportaal.ee).

Your PSA level <3ng/ml indicates a low risk of prostate cancer, and you do not need any additional examinations. This means that your participation in the study has ended. We will ask you to give feedback on the study coordination. Health monitoring should be continued according to the recommendations of your family physician.

If your PSA level is ≥3ng/ml, it means that you will need additional examinations. Together with your PSA-test result, you will receive instructions on how to make an appointment with a urologist. You can choose a suitable time and healthcare facility (Tartu University Hospital, North Estonia Medical Center, or East Tallinn Central Hospital).

During your visit to the urologist, you will have an examination and be asked a few questions. Based on these data, your prostate cancer risk score will be calculated using a specific risk calculator. If the risk score is low, your participation in the study will end. We will ask you to give feedback on the study coordination. Health monitoring should be continued according to the recommendations of your family physician.

If the risk score exceeds a threshold, the urologist will refer you for an MRI (magnetic resonance imaging) scan. After the MRI, you will visit the urologist again, where you will receive further instructions based on the MRI findings. Depending on MRI results, a prostate biopsy may be necessary.

Please be assured that you will receive all necessary diagnostic examinations and/or treatment.

WHY SHOULD I PARTICIPATE IN THE STUDY?

Prostate cancer is the most common cancer in men, and it can be successfully treated when detected early. In the early-stages, prostate cancer may not cause any complaints, but screening enables detecting cancer even in the absence of symptoms.

WHAT ARE THE POSSIBLE RISKS?

Bruising may occur at the site of puncture. If you need additional examinations, you will be informed of the risks before undergoing any procedures.

Give yourself a gift of confidence by participating in the study of early detection of prostate cancer!

The study is carried out by the National Institute for Health Development (env@tai.ee) in collaboration with the Estonian Association of Urology, Estonian Health Insurance Fund, Tartu University Hospital, North Estonia Medical Center, East Tallinn Central Hospital, and SYNLAB Estonia.

Additional information and the contacts of healthcare clinics can be found on this website: tai.ee/env

You may stop participating and withdraw your consent at any time. This means that you will no longer be invited to further examinations, and any data collected previously will be anonymized.

If you have had a PSA test within 12 months or decided not to participate for other reasons, we kindly ask you to explain your decision here: <u>tai.ee/env</u> Your response will be recorded anonymously.

We confirm that your personal data is protected and processed in accordance with the General Data Protection Regulation, the Personal Data Protection Act, other relevant legislation, and principles of good research practice. Health data are collected during research activities. Only investigators and laboratory staff have access to personal data. Once data collection has ended, personally identifiable information will be removed, and further analysis will take place in pseudonymized format. Your data will be shared with pan-European PRAISE-U study network in pseudonymized form. Summaries and results of the study will be published in a generalized form. Personal data will be permanently deleted no later than December 31, 2035. Samples will be stored in the laboratory for up to three months. The research protocol has been approved by the Research Ethics Committee of the National Institute for Health Development.











