Detecting Abdominal Aortic Aneurysms in First Degree Relatives (Adult Offsprings) to AAA Patients (DAAAD)

INFORMED CONSENT FORM TRANSLATED TO ENGLISH FROM SWEDISH FORM

Ethic application Approved of the study plan and informed consent form
Dnr: 2019-01076 Stockholm Sweden

I give my approval for the attached SAP, dated 2020-10-02

Author: Rebecka Hultgren, Anneli Linne

Statistician Reviewer: Sverker Svensjö

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KAROLINSKA UNIVERSITETSSJUKHUSET

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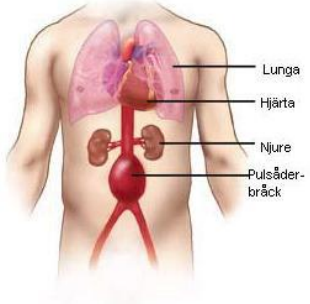
Request for participation in a scientific study regarding abdominal aortic aneurysms

We invite you to participate in a health check for early detection of abdominal aortic aneurysms. Participation in the study is voluntary and you are offered a free ultrasound examination.

Abdominal aortic aneurysms means that the lower part of the aorta has been enlarged. The reasons for this may be hereditary or due to the fact that the vessel wall has been weakened by atherosclerosis or smoking. Through early detection, the aneurysm can be treated to avoid future rupture. The disease is more common in men than women and the risk of developing the disease increases with age. An early-detected abdominal aortic aneurysms can be treated, and it is therefore important to find this group of people.



Why do we invite you?

It is known that there is a certain increased risk of developing abdominal aortic aneurysms for siblings of people with the disease. Approximately 3–15% of those examined who have a relative with the disease are expected to have a this if they are older than 50 years. It is not certain that adult children of people who have had this have an equal risk of developing abdominal aortic aneurysms, but it is likely that they have an increased incidence of this disease. In the Swedish health registers, ie where people who have been cared for in hospital or have had contact with health care due to this disease can be found, a large number of people with abdominal aortic aneurysms have been found. Their first-degree relatives in Sweden have since been identified in the Swedish multigenerational register. In this study, half of the people invited have a relative with the disease, and half do not have a known relative with the disease. When the survey is conducted, the investigator does not have access to information about which group you belong to, as this is confidential information. We have received your address information from national registers.

What will happen?

You who choose to participate in the study will have to answer three questionnaires that take a total of about 5-10 minutes to complete. This is done before the ultrasound examination. You will find your serial number for the surveys at the summons. Once in place, the ultrasound examination of the abdomen is performed, ie weak ultrasound waves are sent into the body, which has been proven to be completely harmless. The examination is painless and takes between 10-20 minutes to complete. If you do not have an aneurysm in your abdomen, you will receive an answer immediately, and thus your study participation is terminated.

If the examination should show that you have an aneurysm, you will receive an information brochure and a booked doctor's appointment at a vascular surgeon's surgery within two weeks for further information and planning for treatment or further checks. At the vascular surgery clinic, you will receive much more detailed information about the disease and its continued care. You will also receive contact information for us to be able to reach us if questions arise during the waiting period. Your continued treatment will then be performed in the same way as for all other patients with this diagnosis in Stockholm

We who invite you to the survey

We who carry out this study are vascular surgeons who work at several vascular surgery clinics in Sweden. The study aims to find a better system for detecting a aneurysms in adult children of patients who we know have had or have this disease. More information about the disease is available at www.vardguiden.se
The invitation is personal. In the invitation that accompanies this letter, you will find how you can rebook your time or get in touch with us in the research group. If you have undergone an examination of your aorta within the last 2 years, you can participate in the study without being examined. You may already know that you have an aneurysm, or have undergone treatment for it. In order for the study to be as complete as possible, this information is very helpful. Please provide such information in the comments section below or when you contact us.
Karolinska Institutet takes responsibility for your personal data and that these are handled in accordance with the Data Protection Ordinance (GDPR). Your answers and your results will be processed so that unauthorized persons cannot take part in them. Our contact information is below. Statistics Sweden (SCB) has, after an ethical examination, approved to identify adult children via patients in national hospitals and causes of death and found a similar group of people who have no relatives. Statistics Sweden has subsequently sent this invitation which we have written to you. Statistics Sweden does not participate in the study or its implementation in general. They are most easily contacted at scb@scb.se, and have the visiting address Karlavägen 100 in Stockholm.

We ask you to bring this form to the ultrasound examination!

If you have any questions regarding the study or study, do not hesitate to contact us:

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Telefonnummer: 08-123 941 51: Telefonsvarare; lämna meddelande så ringer vi upp.
Huvudansvarig forskningsledare: Rebecka Hultgren, Läkare,
ME Kärlkirurgi, Karolinska Universitetssjukhuset,

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Södersjukhuset, Karolinska Institutet. Anneli.linne@sll.se

Consent form:

I approve of participation in the study. I have received oral and written information about the study and have had the opportunity to ask questions. I understand that I may terminate my participation in the study at any time without giving reasons. Participation is voluntary.

Participant

Date and city: _____

Name: _____

Signature _____PIN _____

Nurse/researcher _____

Date and city: _____

Name: _____

Signature _____

Sjukhus och Universitet som deltar i projektet:
Södersjukhuset, Karolinska Universitetssjukhuset, Karolinska Institutet, Stockholm.