Patient information leaflet and invitation to participate

You are invited to participate in a screening study of the colon (large intestine) that is conducted on behalf of Swedish County Councils and the Regional Cancer Centres (RCC). RCC Uppsala-Örebro is responsible for the study. The Ethical Review Board has approved the study.

Aim and background
The aim of the study is to determine whether screening can reduce the risk of colon cancer, as well as dying of the disease once it has developed. Colon cancer is common—approximately 6,000 Swedes are diagnosed every year, and the risk of dying from the disease once it has developed is greater than 40%. Research has shown that early detection considerably reduces the risk of dying. Furthermore, most tumours in the colon start off as polyps, which are protuberances in the mucous membrane. Detection and removal of polyps can prevent colon cancer from developing. Both polyps and colon cancer leave traces of blood in the stool that are invisible to the eye.

Study design
A total of 270,000 people age 59-62 have been randomly selected from the Swedish population register to participate in one of the following three groups:

1. A total of 30,000 people are being invited to be examined with colonoscopy once.
2. A total of 60,000 people are being invited to provide stool samples on two different occasions (year 1 and year 3). Those whose samples show signs of blood will be offered a colonoscopy.
3. A total of 180,000 people will represent the Swedish population and be monitored through national registers.

You have been randomly selected to participate in group 2

If you decide to participate, send us the two fecal immunochemical tests in the envelope both enclosed in this mailing. If the test turns out to be positive (contains a certain quantity of blood), you will receive an appointment at the regional hospital for a colonoscopy. We will send you the results of the test within four weeks after we receive it from you.

Fecal immunochemical test (FIT)

Follow the attached instructions.

FIT is a method for detecting blood in the stool. Taking the test at home is fairly easy. It is important to avoid that the stool come in contact with urine or water in the toilet. Use the enclosed disposable toilet seat cover. You can flush it down the toilet afterwards. Collect samples in two test tubes on different occasions, preferably two days in a row. Send us the tests as soon as possible.

If the results are negative, we will tell you in writing and you will receive new test tubes two years later. If the results are positive (a certain quantity of blood in the stool), we will

inform you by mail within four weeks. You will also receive a separate letter from the hospital where you will be examined with colonoscopy will and you will obtain the date and time of your appointment. Call the hospital to confirm or reschedule your appointment and to obtain the laxative or ask any questions you might have.

We would like to keep your sample in Karolinska Institutet Biobank after analysing it. We want to determine whether bacteria in the stool differ depending on whether there are any cellular changes (polyps) in the colon. We will keep your sample in the biobank unless you notify us otherwise. If you have a colonoscopy, you will be asked to leave a blood sample so that we can study the genes that influence the development of colon cancer. If we detect any cell changes in your colon and take a biopsy, we would also like to keep some of it in order to analyse changes that influence the development of colon cancer. You can at any time request that samples taken during your examination should be discarded.

Colonoscopy and laxative

Colonoscopy

A long, narrow, flexible tube with an optical device in front is inserted into your bowel from behind and through your bowel to the lower part of your small intestine in order to inspect the mucous membranes. If you experience the examination as unpleasant or painful, we will give you a sedative or analgesic as needed. If we detect any cell changes in your colon, we will take biopsies to analyse any changes that influence the development of cancer. We can remove minor cell changes during the colonoscopy. If we detect any polyps, we generally recommend follow-up colonoscopies to make sure that new ones have not formed. In very rare cases, the colonoscopy is not complete and you will then be asked to be examined by radiology examination, called a CT scan, of the colon. This is in no way painful, but requires cleaning of the intestine, and as with all radiology examination, this means that you will be exposed to a small amount of radiation.

Bowel cleansing

There should not be any stool in your colon if we are going to detect any polyps or other cell changes. In order to remove all stool from your colon, you will drink relatively large quantities of the laxative and liquids. The hospital where the colonoscopy is performed will send you more detailed instructions. Laxative prep takes several hours and may make you feel uncomfortable. Hundreds of thousands of Swedes have taken the prep over the past 20 years and there is no medical risk involved.

Risks of colonoscopy

On rare occasions, the tube or any treatment you receive may puncture the wall of the colon. The risk is less than one in a thousand. If that happens, you might have to remain at the hospital for observation. Any biopsy we take after having detected a cell change will cause a little bleeding in the wall of the colon—this is a normal and the bleeding generally stops very quickly. In rare cases, there might be so much bleeding that it is visible in the stool. If you notice any blood, have severe pain or experience other discomfort after returning home, make sure to contact the hospital.

Your participation

This invitation is personal, voluntary and all examinations is free of charge. You can drop out of the study at any time and this will not affect your future care or treatment. Your participation is important for us, to determine whether screening can prevent and reduce the risk of dying from colon cancer. You should not participate if you have been treated for colon cancer.

Confidentiality

Your personal data and all information that we collect in the study is treated as confidential in accordance with Official Secrets Act, which means that no unauthorized person has access the data. When the study data is calculated and reported all information is anonymous and no unauthorized person can see what data comes from a single individual. Karolinska Institutet is responsible for your personal data in the study. All data are treated according to EU/ GDPR, you have a right to know what personal information that has been processed about you in the study. You can get an extract showing this information free of charge once a year following a written request addressed to Karolinska Institutet or the following contact persons below. If it appears that any information is incorrect you have a right to get this corrected or deleted.

More details about the study are available on the RCC Uppsala Örebro website:
http://www.cancercentrum.se/uppsalaorebro/

Feel free to call the following SCREESCO contacts if you have any questions about the study.

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Telephone hours:
Monday and Wednesday, 1:00–3:00 pm
Tuesday, Thursday, Friday, 10:00 am–12:00 noon

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