

## INVITATION TO PARTICIPATE IN A PHD STUDY

### **Clinical outcome, cine MRI and microbiological mesh analysis after ventral hernia mesh repair with open or laparoscopic technique.**

Dear Mr/Ms.....

You are invited to participate in a project to improve the outcome of hernia surgery. It is all up to you if you want to join the project or not. If you feel reluctant, take your time and discuss it with family or friends.

If you decide to participate, kindly fill in this form and bring it with you at your appointment.

The project has three different parts. The part that is applicable for you is marked with an asterix (\*)

- 1) All patients with a history of ventral hernia surgery at our hospital from January 2000, will be invited for a clinical exam of the abdomen. We will address questions about your experience with the operation and the time after the operation. We will ask about abdominal pain and if you are satisfied or not with the surgical result. ( )
- 2) We are interested to know if your Quality of life has improved after the operation. If your hernia never have been operated we also want you to report your Quality of life. Enclosed you will find three types of forms: Sf-36 which measures physical, mental, social and emotional factors concerning your everyday life. Activity assessment scale which measures your physical well-being and Life orientation test which tells if you are optimistic or no. Please fill out, and leave questions blank if You don't understand the question completely. ( )
- 3) If you have a new hernia after the former hernia operation and that gives you complaints of a certain magnitude, we will discuss different options. If a new hernia operation is recommendable, we will invite you to presurgical X-ray ( see item 4) and new hernia operation ( see item 5)
- 4) X-ray or diagnostic imaging has some clear benefits: We can judge the size of the hernia and see if there are more than one hernia. We will also be able to see if your abdominal wall is strong or weak and if there are other factors that helps us in treatment planning ( ) We prefer to have this done by MRI. If you wish to participate, you will have a form at the reception to see if there are no contraindications for the imaging ( )
- 5) If a new hernia operation is helpful to relieve your complaints, we will ask you to join us in a project to see if the old mesh contains bacteria. During the operation, a small sample (1 x 1 cm) of the old mesh covering the abdominal wall, will be harvested for analysis. We will use a special technique with DNA analysis of the mesh sample to find the exact bacterial species. ( )

We may have to stop the study or take you off the study due to various reasons. We can do this without your consent.

You can also stop participating at any time and if you do so, you will not lose any benefits.

### **RISKS**

This study involves no risk except what follows every hernia operation.

**BENEFITS TO TAKING PART IN THE STUDY?**

There are no benefits for you except having your hernia repaired if that is the issue. Beyond this, knowledge about every aspect of hernia disease and its treatment, will benefit future hernia care.

**CONFIDENTIALITY**

All the participants and the information we gather in our study will be kept discreet and secured. It is only the researcher taking part in this project that can open the database with all information about the project and the participants.

Any publisher who would ask for this data to check its validity, is entitled to do so. In case of publishers request, we guarantee that all information about you is anonymized.

**INCENTIVES**

We can not offer any economical benefits for an participant.

**YOUR RIGHTS AS A RESEARCH PARTICIPANT**

Participation in this study is voluntary. You have the right not to participate at all or to leave the study at any time. Deciding not to participate or choosing to leave the study will not result in any loss of benefits to which you are entitled, and it will not harm your relationship with Akershus University Hospital.

**APPROVAL**

The study is approved by the Data protection official for research at Akershus University Hospital. Item 5 is also approved by the Regional Ethics Committee.

**RESEARCH FELLOW**

If you have any questions about the study, please be free to call or mail:

Call Dr. Odd Langbach at 679 64 421 or [email\\_odd.langbach@ahus.no](mailto:odd.langbach@ahus.no)

Signature

Place

Date

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