Consent form for participation in study on prevention of hernias in the abdominal wall

(NoPro – Norwegian Hernia Prophylaxis Study)

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Project title: NoPro - Norwegian Hernia Prophylaxis study: Onlay mesh versus small bite suture technique closure of midline laparotomies.

REK number: 761933

Project managers:

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Purpose of the project and why you are being asked to participate

You are scheduled for surgery, which may involve either a laparotomy (an open surgery) or laparoscopic technique. In some cases, laparoscopic surgery may require converting to open surgery. By participating in this research, you will help us explore what is the best method for closing the abdominal wall to prevent incisional hernias following open surgery.

What is an incisional hernia?

An incisional hernia occurs when the muscles around a surgical scar separate, allowing contents from the abdominal cavity to bulge through the opening and into the subcutaneous tissue. Incisional hernias are a common complication after surgeries that involve large incisions in the abdominal wall. Many patients experience symptoms and require further surgery to repair the hernia. Over time, hernias tend to expand. Studies show that 9% to 39% of patients develop an incisional hernia after laparotomy. The risk varies depending on patient characteristics, surgical techniques, and how the abdominal wall is sutured after the surgery. The type of thread used for suturing also plays a significant role, and there are established guidelines for best practices based on research findings.

What we know from previous studies

When repairing an incisional hernia, a large mesh is often used to reinforce the area around the scar. Studies suggest that placing a smaller mesh preventively during the initial surgery significantly reduces the risk of developing an incisional hernia. Both European and American guidelines support mesh reinforcement for closing the abdominal cavity but do not mandate its use.

How the project will affect you

If you agree to participate, you will be randomly assigned to one of two groups. In one group, the abdominal wall will be sutured with the recommended thread. In the other group, the same suturing method will be used, but an additional polypropylene mesh will be applied over the scar area (3 cm in all directions) to reinforce the closure. Every Monday, a random draw will determine which group patients scheduled for surgery that week will be placed in. You will not know whether you received the mesh until your 1-year follow-up.

All participants will be invited for follow-up visits at the outpatient clinic 4-6 weeks and 1 year after surgery. During the 1-year follow-up, a CT scan will be performed to detect any signs of a hernia, and the results will be reviewed by a radiologist. You will also undergo a clinical examination (visual inspection and palpation), and you will be asked to complete questionnaires about your quality of life and pain levels both before the surgery and during follow-ups. If you develop a hernia after surgery, you will be offered hernia repair surgery during the 1-year follow-up, given that you have symptoms, and your overall health allows the procedure.

Eligibility for participation

You may participate in this study if you meet the following criteria:

- You are undergoing a surgery involving a large incision through the midline of the abdominal wall (though it may begin as laparoscopic surgery).
- You are 18 years of age or older.
- You have not previously had hernia surgery with mesh implantation in the same area of the abdominal wall and do not have a hernia with an opening larger than 2 cm in diameter.
- You are not pregnant.
- You are not allergic to polypropylene.
- You can provide informed consent (you know who you are, where you are, and why you are undergoing surgery).
- You have a life expectancy of more than 6 months.

Possible benefits and risks

The use of a reinforcing mesh may reduce the likelihood of developing an incisional hernia. European guidelines allow for mesh reinforcement when closing the abdominal wall, though it is not commonly used in Norway. By participating, you may not receive a mesh, which could be beneficial for those at higher risk of hernias (e.g., individuals with obesity, diabetes, COPD or a smoking history).

One potential side effect of mesh use is seroma (fluid accumulation under the skin), which is generally harmless and resolves on its own. If the fluid persists, it can be drained either through a small incision or with a catheter placed in the radiology department. To prevent seroma, a drain will be inserted during surgery to remove any excess fluid, and it will be removed once no more fluid is collected. Some patients who do not receive the mesh may also need a drain if there is a significant risk of infection at the surgical site.

Infections at the incision site are another concern, though previous studies have not found evidence of an increased risk associated with mesh. One of the study's objectives is to assess whether mesh increases the risk of infection.

Additionally, one year after your surgery, you will undergo a CT scan to check for an incisional hernia. For many patients, this CT scan is already part of the standard follow-up care, but for some, it will be an additional scan that introduces extra radiation exposure. Although the dose is low, accumulated radiation over time can increase the risk of certain cancers, including blood cancers.

Voluntary participation

Your participation is entirely voluntary, and you may withdraw at any time without needing to provide a reason. If you choose to withdraw, you will not be invited for the 1-year follow-up unless required for another medical reason. Any data collected up until the point of withdrawal will be anonymized and will not be further used in the study unless it has already been included in the analysis. In that case, we will keep the anonymized data.

Handling of personal information

Your personal information will be stored securely on a protected server at Innlandet Hospital. Each participant will be assigned a unique study number, and your personal details will only be accessible to the project leaders: Jorunn Skattum, Jan Lambrecht, and Gjertrud Hole Kjøstolfsen. No identifiable information will be published. Information related to the study will be noted in your digital hospital records, and all data will be stored for 9 years for long-term follow-up, in accordance with ethical approval from REK (Regional Committee for Medical and Health Research Ethics). If you have any questions about the handling of personal information in the project, you can contact Personvernombudet at Innlandet Hospital: personvernombudet@sykehuset-innlandet.no

Follow-up project

We would like to have the possibility to contact you 5 years after surgery to assess the long-term effects of laparotomy and mesh reinforcement. This study will help increase understanding of the risks of hernias over time, particularly regarding the preventive use of mesh. You will be asked for separate consent for this long-term follow-up.

Approvals

This study has been approved by the local data protection officer and the Regional Committee for Medical and Health Research Ethics (REK number 761933).

Contact Information

If you have any questions or wish to withdraw from the study, please contact one of the project leaders:

- Gjertrud Hole Kjøstolfsen: gjertrud.hole.kjostolfsen@sykehuset-innlandet.no | Phone: +47 464 32 356
- Jorunn Skattum: jorunn.skattum@sykehuset-innlandet.no | Phone: +47 932 53 940
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Consent declaration

I have received written and verbal information about the study project NoPro. I consent to participate in the project and for my personal information to be used as described above.

Location and date	Participant's signature
	Name in capital letters

I also consent to being contacted 5 years after the surgery.

Location and date	Participant's signature
	Name in capital letters