

PROJECT INFORMATION/file content:

Patient consent form

Document date: June 26 2020

Project title:

LAPAROSCOPIC REPAIR OF OSTOMY HERNIA WITH MESH OUTSIDE OF THE ABDOMINAL CAVITY

NCT number:

NCT04440514

#### Purpose

This is a request for participation in a quality study, where the purpose is to document the outcome of treatment for hernia in stoma. I am planning a summary of the experiences of all those who have received treatment with the surgical method.

#### How your information is used

Only relevant information is mentioned, such as the classification of the hernia, technical challenges and whether there have been problems in the process. The average age and weight as well as how long the stoma has been are also discussed. You can not be recognized in the published material.

#### About hernia in stoma and surgery

Hernia of the stoma is a very common problem and can cause problems with swelling, stopping stools, pain, skin problems and leakage. Treatment for hernia in the stoma is most often a support bandage, as surgery is difficult and has a high risk of recurrence of hernia. When using nets for reinforcement, better results have been obtained, but still at least 15% have relapses. The most commonly used method today is a peephole operation where you place a net over the opening in the abdominal wall inside the abdominal cavity and the intestine runs a short distance between the net and the abdominal wall. The method is called modified Sugarbaker operation. Nets inside the abdominal cavity can cause problems with adhesions against the intestines to the net and since the net must be attached to the peritoneum, it also gives more pain after surgery, which can last in some cases.

#### About the surgical method and what to evaluate

The method you have operated on is according to the same principle, but instead of laying a net inside the abdominal cavity, a pocket is dissected between the abdominal wall and the peritoneum so that the net can be placed outside the abdominal cavity. This eliminates the disadvantages of nets in the abdominal cavity, while maintaining the low risk of inflammation we know with peephole surgery. This variation of the method is new, somewhat more technically demanding to perform and does not have a proper name yet, so I call it the ePauli method, as Dr. Pauli has described the principle of open surgery (the e stands for endoscopy = peephole). Whether there is less risk of relapse is too early to assess, but there is no reason to believe that there should be greater risk. I want to follow how everyone who has undergone surgery with the method is doing to document the effect, assess whether the method has deviating outcomes and discover whether there are pitfalls with the method we have not anticipated. I would like to ask permission to contact you by phone for an interview about the course and your opinion of whether the treatment has been a success, as well as some details about what one could have wished had fallen out in another way. I will also ask you to sign the attached consent form, which is a prerequisite for me to be able to use your data in scientific reports. I will present the results in international peer-reviewed medical journals as well as at conferences and in teaching. The hospital has video documentation of all peephole operations and I will use this material in closed professional gatherings - without you being recognized.

#### Data processing and consent

All project data will be stored in a securely stored area, which only the project manager has access to. The Privacy Ombudsman at Sykehuset Innlandet HF has, on behalf of Sykehuset Innlandet HF, assessed that the processing of personal data in this project is in accordance with the privacy regulations. It is voluntary to participate in the project. By signing the consent sheet, you accept participation. If you do not wish to participate, you can withdraw at any time without giving any reason and without this having any negative consequences for you in further treatment or follow-up. You can withdraw your consent by contacting the project manager, see the email address below, or notify the surgical secretariat at the hospital in Hamar.

- Information we process about you is based on consent.

Consent form must be returned in the enclosed postage-paid envelope.

With best regards

Project manager and treating surgeon:

Consultant PhD Jan Lambrecht

Department of Gastrosurgery, Sykehuset Innlandet HF

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Privacy representative at Sykehuset Innlandet HF:

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#### DECLARATION OF CONSENT

I have received oral and written information about the project Yes No

I allow anonymized video recording from surgery to be used for teaching

peers Yes No

Signature and consent:

Date:

Name in block letters:

Signature: