

Closing of the hernia defect during laparoscopic ventral hernia repair

Submission date 15/02/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 22/04/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/09/2025	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol

Background and study aims

A ventral hernia is a bulge of tissues through an opening (or defect) within the abdominal wall muscles. They can sometimes cause symptoms such as pain in the abdomen, outward bulging of skin or tissues, nausea and vomiting. This study is comparing two different ways of performing laparoscopic (keyhole) ventral hernia repair. The aim is to test the effect of closing the defect with a suture (stitches) before reinforcement using a mesh.

Who can participate?

Adults (over 18) with a ventral hernia which has not previously been repaired with a mesh.

What does the study involve?

Participants are randomly assigned to one of two groups. Group 1 has a laparoscopic ventral hernia repair with the defect sutured before using the mesh. Participants in group 2 have their mesh applied without closing of the defect with a suture. All participants are then assessed at 3 months and then again at 12 months for complications. They also have a CT scan at 12 months. Tissue samples (biopsies) are also taken from the skin, muscle Biopsy from skin, muscle and fascia (connective tissue) are taken and analysed.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Skellefteå hospital

Mora hospital

Ersta hospital

Enköping hospital (Sweden)

When is the study starting and how long is it expected to run for?

April 2015 to November 2021

Who is funding the study?

1. Västerbotten County Council
2. Visare Norr (cooperation northern counties)

Who is the main contact?

Mr Mikael Lindmark

Contact information

Type(s)

Scientific

Contact name

Mr Mikael Lindmark

Contact details

University Hospital of Umeå (Norrlands Universitetssjukhus)

Umeå

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901 85

Additional identifiers

Protocol serial number

ML2

Study information

Scientific Title

Prospective RandOmised Study of Endoscopic fascia Closure and long term Outcome

Acronym

PROSECO

Study objectives

Suture of hernia defect before application of mesh prothesis for laparoscopic ventral hernia repair improves the surgical outcome measured as "hernia site complications" (see primary outcome measures below).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional ethics board Umeå (SE), 18/06/2015, ref: 2015-215-32M

Primary study design

Interventional

Study design

Double-blinded randomized controlled multicenter trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Ventral hernia

Interventions

The classic approach in laparoscopic ventral hernia repair is to bridge the hernia defect by reinforcement material. In open techniques, a long- established principle is to, when possible, recreate the anatomy during surgery by suturing of the defect. There is an emerging interest in closing the defect in laparoscopic surgery for ventral hernias before the prosthetic material is applied.

Participants are randomly assigned to one of two groups. They all have a laparoscopic ventral hernia repair, but with the following differences:

Group 1: Undergo suture of hernia defect before application of mesh

Group 2. Mesh is applied without closing of the defect

All participants are then assessed for hernia site complications that occur within 12 months including seroma, hematoma, bulging, mesh migration and infection.

All participants are then assessed for hernia site complications at clinical control after 3 and 12 months. All participants undergo CT scan at 12 months. Hernia site complications include seroma, hematoma, bulging, mesh migration and infection. Biopsy from skin, muscle and fascia are taken and collagen structure will analysed.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Hernia site complications within twelve months. This includes recurrence of the hernia, sustained clinically significant seroma, and clinically significant and symptomatic pseudo hernia with sliding of the reinforcing material into the aneurysm sac after twelve months.

Key secondary outcome(s)

1. Abdominal wall pain, assessed using the Ventral Hernia Pain Questionnaire, before surgery, 3 months after surgery and after 12 months
2. Surgical complications within three months of such as infection, and fistula
3. Operating time
4. Abdominal function measured by Biodex after 12 months

Completion date

01/11/2021

Eligibility

Key inclusion criteria

1. Age >18 years
2. Understand written information in Swedish
3. Primary or incisional hernia of the midline between 2 and 8 cm

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

192

Key exclusion criteria

1. Recurrence after previous hernia surgery
2. Laparoscopy not feasible

Date of first enrolment

18/11/2015

Date of final enrolment

16/09/2020

Locations**Countries of recruitment**

Sweden

Study participating centre

Skellefteå Hospital (Skellefteå lasarett)

Sweden

931 41 Skellefteå

Study participating centre

Mora hospital (Mora lasarett)

Sweden

792 51 Mora

Study participating centre
Ersta hospital
Stockholm
Sweden
116 28

Study participating centre
Enköping hospital
Enköping
Sweden
745 38

Sponsor information

Organisation
Västerbotten County Council

ROR
<https://ror.org/04xvhsp09>

Funder(s)

Funder type
Government

Funder Name
Visare Norr (cooperation northern counties)

Funder Name
Västerbotten Läns Landsting

Alternative Name(s)
Västerbotten County Council

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan

The dataset includes information making it possible to identify unique individuals, therefore in relation to their ethical statement and Swedish law the researchers have to handle it confidentially.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Study website	30/12/2023	03/01/2024	Yes	No
Results article		02/09/2025	04/09/2025	Yes	No
Study website		11/11/2025	11/11/2025	No	Yes