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Closing of the hernia defect during laparoscopic ventral hernia repair

Submission date	Recruitment status	[_] Prospectively registered
15/02/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/04/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/01/2024	Digestive System	

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

Study website
http://www.norrlandskirurgi.se/Randomisera/

Contact information

Type(s)
Scientific

Contact name
Mr Mikael Lindmark

Contact details
University Hospital of Umeå (Norrlands Universitetssjukhus)
Umeå
Sweden
901 85

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Double-blinded randomized controlled multicenter trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Please use contact details to request a participant information sheet

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 measure

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.

Secondary outcome measures
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

Overall study start date
08/04/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
180

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

Sponsor details
Landstingshuset
Köksvägen 11
Umeå

Sweden
901 85

Sponsor type
University/education

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

Publication and dissemination plan

Intention to publish date
30/06/2023

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		30/12/2023	03/01/2024	Yes	No