

Laparoscopic Bridging vs anatomic Open Reconstruction for midline abdominal hernia mesh repair

Submission date 10/10/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/12/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/10/2013	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims:

This study aims to compare two different surgical procedures to treat hernias.

Who can participate?

Male and female participants aged over 60 years, diagnosed with a hernia.

What does the study involve?

Participants will be randomly allocated to one of two groups:

In GROUP R (Reconstruction) - patients will be given the Rives-Stoppa procedure for the repair of the defect.

In GROUP B (Bridging) - patients will be operated on according to standard techniques.

What are the possible benefits and risks of participating?

There will be no immediate benefit to those taking part. However, there should be benefits to patients undergoing hernia repair in the future. There are few risks to the patients taking part and they should not experience any discomfort because he/she will undergo standard surgery by experienced surgeons in the field.

Where is the study run from?

University of Genoa in collaboration with University of Naples.

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

The study will start in December 2012; recruitment will take 12 months and the study is due to end in December 2014.

Who is funding the study?

Sahlgrenska University Hospital, Gothenburg and Swedish Research Council, Sweden.

Who is the main contact?
Dr Cesare Stabilini
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Laparoscopic Bridging vs anatomic Open Reconstruction for midline abdominal hernia mesh repair: Long term functional results - Multicenter Randomized Controlled Trial

Acronym
LABOR

Study objectives
We hypothesize that a laparoscopic bridging of an abdominal wall hernia (primitive or incisional) could have the same effect in terms of functional result in comparison to an anatomical reconstruction by open approach.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicenter non inferiority single blind randomized controlled trial

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Surgical mesh repair of incisional and ventral hernias

Interventions

The patient will be divided in two groups according to the procedure they will undergo:

GROUP R (reconstruction)

Planned number of patients will be submitted to a Rives-Stoppa procedure for the repair of the defect with a lightweight macroporous mesh as described.

GROUP B (bridging)

In this group, patients after randomization will be operated according to standard laparoscopic technique.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Postoperative variations in double leg lowering test (DLL) at 6 and 12 months (as compared to preoperative)

Key secondary outcome(s)

1. Differences in Trunk raising test (TR test) at 6 and 12 months
2. Differences in Abdominal Wall Strength (AWS) score at 6 and 12 months
3. Differences in respiratory function tests at 6 and 12 months
4. Differences in intrabdominal pressure (IAP) pre and postoperative
5. Differences in pain assessed with Visual Analogue Scale (VAS) at 6 and 12 months
6. Differences in quality of life using SF-36 at 6 and 12 months

Completion date

30/11/2014

Eligibility

Key inclusion criteria

1. Patients with a midline incisional or a ventral primitive hernia
2. Dimension measured on preoperative CT scan:
 - 2.1. Primary ventral hernia ≤ 10 cm in its greatest diameter \leq according to EHS classification)
 - 2.2. Incisional hernias W2 according to EHS classification
3. Both sex
4. 60 years of age
5. BMI < 35 Kg/m²
6. Give informed consent for randomization

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients with non-midline defects or diastasis recti without herniation
2. Hernia with a previous attempt of mesh repair
3. Hernia is near to a bony salience
4. Patient is classified as American Society of Anesthesiologists class 4 or 5
5. Patient has a severe comorbid condition likely to limit survival to 2 years
6. Patient has cirrhosis with or without ascites
7. Patient is under immunosuppressive treatment has received previous bariatric surgery
8. Patient has bowel obstruction, strangulation, peritonitis, or perforation;
9. Presence of local or systemic infection
10. Neuromuscular disease likely to impair motility (e.g. previous ictus with reliquate)
11. Patients refusing to participate to the study

Date of first enrolment

01/11/2012

Date of final enrolment

30/11/2014

Locations**Countries of recruitment**

Italy

Study participating centre

via Nizza 4

Genoa

Italy

16145

Sponsor information**Organisation**

University of Genoa (Italy)

ROR

<https://ror.org/0107c5v14>

Funder(s)

Funder type

University/education

Funder Name

University of Genoa (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/10/2013		Yes	No