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

Submission date	Recruitment status	[_] Prospectively registered
10/10/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/12/2012	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/10/2013	Digestive System	[_] 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
cesarestabil@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Cesare Stabilini

Contact details
via Nizza 4
Genoa
Italy
16145

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
1. Differences in Trunk raising test (TR test) at 6 and 12 months
2. Differences in Abdominal Wall Strenght (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

Overall study start date
01/11/2012

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 ¡Ý4 d ¡Ü10 cm in its greatest diameter ¡°large¡± according to EHS classification)
2.2. Incisional hernias W2 according to EHS classification
3. Both sex
4. 60 years of age
5. BMI<35Kg/m2
6. Give informed consent for randomization

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

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. Neuromuscolar 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)

Sponsor details
Department of surgical sciences (DISC)
L.go Rosanna Benzi 8
Genoa
Italy
16132

Sponsor type
University/education

ROR
https://ror.org/0107c5v14

Funder(s)

Funder type
University/education

Funder Name
University of Genoa (Italy)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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