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Low density versus high density meshes in patients with bilateral inguinal hernia

Submission date
12/04/2015

Recruitment status
No longer recruiting

Registration date
24/06/2015

Overall study status
Completed

Last Edited
24/06/2015

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A hernia can occur when a weak spot in the muscle or tissue lets an internal part of the body such as the intestines push through. An inguinal hernia occurs in the groin region when fatty tissue or a part of the bowel bulges through into your groin at the top of the inner thigh. When this happens on both sides of the groin it is called a bilateral inguinal hernia. Surgery can be used to push the bulge back into place and a surgical mesh is often used to strengthen the surrounding tissue. There are two types of mesh most often used in surgery to treat hernias. One is lightweight, and the other is heavyweight. The aim of this study is to see whether there is a difference in patients' experience of pain and surgical complications depending on which type of mesh is used to treat their bilateral inguinal hernia.

Who can participate?
Adults over 18 undergoing surgery for bilateral inguinal hernia.

What does the study involve?
All participants are given a lightweight mesh and a heavyweight mesh. One mesh will treat one side of the hernia, and the other mesh will treat the other side; which side gets what mesh is allocated randomly. Questionnaires about pain and health related to the surgery are completed on the 1st, 3rd, 5th, and 7th day after surgery and, finally, one year after surgery.

What are the possible benefits and risks of participating?
Both type of meshes are approved and commonly used in medical practice and their use does not carry additional risk.

Where is the study run from?
The Santa Cristina University Hospital (Hospital Universitario Santa Cristina) (Spain)

When is the study starting and how long is it expected to run for?
May 2006 to June 2008

Who is funding the study?
The Santa Cristina University Hospital (Hospital Universitario Santa Cristina) (Spain)

Who is the main contact?
Miss L Latorre

Contact information

Type(s)
Scientific

Contact name
Miss Lucia Latorre

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Contact details
Maestro Vives 2
Madrid
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28009

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CIRESP-15-34

Study information

Scientific Title
Randomised clinical trial comparing low density versus high density meshes in patients with bilateral inguinal hernia

Study objectives
There is a difference in patient-report of postoperative pain, feeling of a foreign body, postoperative complications, and recurrence of hernia in patients following surgery for bilateral inguinal hernia using either lightweight or heavyweight mesh.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study does not require ethics approval. We compare two meshes that are frequently used in inguinal hernia repair and these are approved for use.

Study design
Randomised prospective interventional clinical trial single-centre

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Bilateral inguinal hernia

Interventions
Lightweight mesh is randomly allocated to patients for use on one side of a bilateral hernia. The more frequently used heavyweight mesh is used on the other side. The side receiving the lightweight mesh is selected using a random numbers table.

Intervention Type
Procedure/Surgery

Primary outcome measure
Outcomes measured on 1st, 3rd, 5th and 7th postoperative day, and one year after surgery:
1. Postoperative pain measured by visual analogue scale
2. Complications following procedure comparing lightweight mesh and heavyweight mesh
3. Self-reported feeling of a foreign body following surgery
4. Recurrence of bilateral inguinal hernia comparing lightweight mesh and heavyweight mesh

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
01/02/2006

Completion date
30/06/2008

Eligibility

Key inclusion criteria

1. Age >18
2. No significant comorbidity
3. Clinical symmetrical hernias
4. Simple non-recurrent hernias
5. No associated femoral hernia
6. Participant consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
67

Key exclusion criteria
1. Age <18 years
2. Senior patients with significant comorbidity
3. Clinically asymmetrical hernias
4. Recurrent hernias
5. Complicated hernias (incarceration or strangulation)
6. Presence of associated femoral hernia
7. Patient cannot give consent

Date of first enrolment
22/02/2006

Date of final enrolment
19/06/2008

Locations

Countries of recruitment
Spain

Study participating centre
The Santa Cristina University Hospital (Hospital Universitario Santa Cristina)
Maestro Vives 2
Madrid
Spain
28009

Sponsor information

Organisation
The Santa Cristina University Hospital (Hospital Universitario Santa Cristina)

Sponsor details
Maestro Vives 2
Madrid
Spain
28009

Sponsor type
Hospital/treatment centre

Website
www.madrid.org/hospitalsantacristina

ROR
https://ror.org/01bynmm24

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Santa Cristina University Hospital (Hospital Universitario Santa Cristina) (Spain)

Results and Publications

Publication and dissemination plan
Publication in peer-reviewed journal Spanish Surgery (Cirugía Española).

Intention to publish date
01/05/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request