

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

Submission date 12/04/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 24/06/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 24/06/2015	Condition category Digestive System	☐ 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

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Contact details

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Spain

28009

Additional identifiers

Protocol serial number

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.

Primary study design

Interventional

Study design

Randomised prospective interventional clinical trial single-centre

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

There are no secondary outcome measures.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request