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Comparing titanium-coated lightweight mesh versus medium-weight composite mesh for laparoscopic hernia repair

Submission date 27/09/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 07/10/2011	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/10/2016	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
A hernia occurs when an internal part of the body pushes through a weakness in the muscle or surrounding tissue wall. An incisional hernia is a type of hernia caused by an incompletely-healed surgical wound. It has become standard practice to use a mesh in hernia surgery. In recent years a new generation of meshes has been developed which have bigger pores with a lower weight or density, which are classified as heavyweight, medium-weight or lightweight. The aim of this study is to test a new lightweight mesh with titanium, which seems to have certain advantages as it provokes a less pronounced foreign body reaction compared with identical meshes lacking a titanium coating.

Who can participate?
Patients with an incisional hernia who are at least 18 years old

What does the study involve?
Participants are randomly allocated into one of two groups. Both groups undergo laparoscopic hernia repair (keyhole surgery), with one group receiving a titanium-coated mesh while the other group receives a collagen-polyester composite mesh. Pain, hernia recurrence analgesic (painkiller) consumption, and time taken to return to everyday activities are measured in both groups.

What are the possible benefits and risks of participating?
The use of lightweight meshes in hernia repair could have beneficial effects on quality of life (less pain, less use of analgesics and faster return to work).

Where is the study run from?
Morales Meseguer University Hospital (Spain)

When is the study starting and how long is it expected to run for?
January 2005 to December 2008

Who is funding the study?
Morales Meseguer University Hospital (Spain)

Who is the main contact?
Prof. Alfredo Moreno-Egea

Contact information

Type(s)
Scientific

Contact name
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Contact details
Primo de Rivera 7, 5ºD
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Spain
30008

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomized clinical trial of laparoscopic hernia repair comparing titanium-coated lightweight mesh versus mediumweight composite mesh

Acronym
Mesh Trial

Study objectives
The use of lightweight meshes in incisional hernia repair could have beneficial effects on quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Morales Meseguer Hospital, 07/08/2004

Study design
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 to request a patient information sheet

Health condition(s) or problem(s) studied
Incisional hernia

Interventions
Group A: laparoscopic hernia repair with lightweight (titanium-coated). Patients n=51
Group B: laparoscopic hernia repair with heavyweight (collagen-polyester composite), patients n=51

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Pain
1.1. Acute pain, defined as pain reported by a patient in the first 6 months after operation
1.2. Chronic pain, defined as pain that persisted for more than 12 months
1.3. Pain scores on a 10-cm visual analogue scale (VAS) were measured from 0 (no pain) to 10 (unbearable pain)
2. Recurrence, confirmed by clinical examination and computerised tomography (CT)

Secondary outcome measures
1. Morbidity
2. Operating time (minutes)
3. Hospital stay (days)
4. Need for oral analgesia (days)
5. The time it took to return to everyday activity (days). This period was defined as the time needed to be able to perform household activities, drive or walk painlessly. An increased analgesic requirement was defined as an analgesic intake which lasted for more than one day.

Overall study start date
01/01/2005

Completion date

30/12/2008

Eligibility

Key inclusion criteria
1. Patients who were at least 18 years old and diagnosed at the Abdominal Wall Unit of Morales Meseguer University Hospital of Murcia with an incisional hernia
1.1. In this study, incisional hernia was defined as any midline abdominal wall gap with a bulge in the area of a postoperative scar perceptible or palpable by clinical examination and imaging (localized between the xiphoid and pubic bone)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Patients with non-midline hernias and a fascial defect greater than 10cm
2. Patients with incisional hernias repaired with a synthetic mesh
3. Those receiving corticosteroid therapy, radiotherapy or chemotherapy
4. Concurrent neoplasms
5. Proven mental illness or other circumstances that might compromise the patients cooperation as well as those who refused to give informed consent

Date of first enrolment
01/01/2005

Date of final enrolment
30/12/2008

Locations

Countries of recruitment
Spain

Study participating centre
Primo de Rivera 7, 5ºD
Murcia

Spain
30008

Sponsor information

Organisation
Morales Meseguer Hospital (Spain)

Sponsor details
Marques de los Velez s/n
Murcia
Spain
30008

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00cfm3y81

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Morales Meseguer Hospital (Spain)

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