Efficacy evaluation of a low weight prosthetic mesh in the prevention of incisional hernia in patients undergoing medial laparotomy surgery

Submission date	Recruitment status No longer recruiting	Prospectively registered		
22/08/2009		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
22/10/2009	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
01/02/2019	Digestive System			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Efficacy evaluation of a low weight prosthetic mesh in the prevention of incisional hernia in patients undergoing medial laparotomy surgery: a prospective randomised single-blind parallel group single centre trial

Study objectives

Placemet of a low weight prosthetic mesh can prevent or reduce the ocurrence of incisional hernia in patients requiring medial laparotomy surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the University Hospital Joan XXIII Tarragona, 27/04/2009

Study design

Prospective randomised simple blind parallel group single centre 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

Incisional hernia

Interventions

Intervention group: At the end of the surgery we close the abdominal fascia with a continuous suture and a low weight polypropilene prosthetic mesh is placed 3 cm above the end zone attached to the aponeurosis with continuous sutures.

Control group: At the end of the surgery we close the abdominal fascia with a continuous suture only.

Intervention Type

Procedure/Surgery

Primary outcome measure

- 1. Physical exploration in series controls, in one week, one month, three months, six months, one year and two years
- 2. Computed tomography (CT) scan in doubt cases

Secondary outcome measures

36-item short form health survey (SF-36) quality of life test at baseline, one month, six months and one year

Overall study start date

01/05/2009

Completion date

01/05/2013

Eligibility

Key inclusion criteria

- 1. All patients aged between 18 and 80 years, both sexes, requiring digestive surgery in our hospital, by a medial laparotomy
- 2. American Society of Anaesthesiology (ASA) less than grade IV

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

71 patients in the control group and 71 patients in the mesh group

Key exclusion criteria

- 1. Allergic to polypropilene
- 2. Previous prosthetic mesh for a previous incisional hernia
- 3. Any ostomy in the abdominal wall
- 4. ASA greater than or equal to grade 4
- 5. Living prognosis less than 12 months
- 6. Corticotherapy
- 7. Haemodialysis

Date of first enrolment

01/05/2009

Date of final enrolment

Locations

Countries of recruitment

Spain

Study participating centre
University Hospital Joan XXIII de Tarragona
Tarragona
Spain
43007

Sponsor information

Organisation

University Hospital Joan XXIII de Tarragona (Spain)

Sponsor details

General Surgery Department Dr. Mallafre Guasch n° 4 Tarragona Spain 43007

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/05s4b1t72

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital Joan XXIII de Tarragona (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2014		Yes	No
Results article	results	01/09/2014		Yes	No
Results article	results	01/04/2019	01/02/2019	Yes	No