

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

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

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

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

Primary study design

Interventional

Study design

Prospective randomised simple blind parallel group single centre trial

Study type(s)

Treatment

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 continous 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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

01/05/2013

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)

ROR

<https://ror.org/05s4b1t72>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital Joan XXIII de Tarragona (Spain)

Results and Publications

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