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

Submission date	Recruitment status	[_] Prospectively registered
22/08/2009	No longer recruiting	[_] 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
Dr Vicente Vicente

Contact details
General Surgery Department
University Hospital Joan XXIII de Tarragona
C/ Dr. Mallafre Guasch nº 4
Tarragona
Spain
43007
-
drvicentevicente@hotmail.es

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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 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 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

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)

Sponsor details
General Surgery Department
Dr. Mallafre Guasch nº 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