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How to prevent the trocar-site hernia? A totally atraumatic endoscopic mini-IPOM-Plug technique (with extra-lightweight titanium coated mesh and glue)

Submission date
16/11/2015

Recruitment status
No longer recruiting

Registration date
01/12/2015

Overall study status
Completed

Last Edited
16/11/2015

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Laparoscopy is a type of surgery that allows a surgeon to access the inside of the body without having to make large incisions in the skin. The arrival of laparoscopy could be regarded as the biggest change in surgical techniques this century. However, there is a negative side to this new approach, such as a new kind of hernia, the trocar-site hernia. A hernia is a weakness or split in the muscle wall of the abdomen which allows the abdominal contents (usually some part of the intestine) to bulge out. With the increasing use of laparoscopic surgery the problem of this new type of hernia will increase too. The surgical placement of a prophylactic (preventive) mesh may help to prevent trocar-site hernia. The aim of this study is to find out whether it is possible to prevent trocar-site hernia after laparoscopic cholecystectomy by placing a prophylactic mesh.

Who can participate?
Patients aged 20-70 undergoing laparoscopic cholecystectomy (gallbladder removal) for cholelitiasis (gallstones).

What does the study involve?
Patients are randomly allocated to either receive a prophylactic mesh or to not receive a mesh during their operation.

What are the possible benefits and risks of participating?
The patients who receive the mesh may be at risk of seroma (collection of fluid) or wound infection at the mesh site. The patients who do not receive the mesh may be at risk of hernia.

Where is the study run from?
La Vega Hospital (Spain).

When is the study starting and how long is it expected to run for?
January 2013 to December 2016.

Who is funding the study?
Universidad de Murcia (Spain).

Who is the main contact?
Prof Alfredo Moreno-Egea
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Prevention of the trocar-site hernia with prophylactic mesh: a randomized clinical trial

Study objectives
The trocar-site hernia is a new complication in laparoscopic surgery which is becoming increasingly prevalent. Thus, the search for an efficient method of prophylaxis should be prioritized.

The aim of this study is to find out whether it is possible to prevent trocar-site hernia (umbilical site) after laparoscopic cholecystectomy using a prophylactic mesh.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hospital General Universitario Morales Meseguer Ethics Committee, 01/01/2013

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Trocar-site hernia

Interventions
Patients were randomized on the day of surgery to receive either a prophylactic mesh in the umbilical trocar site (treatment group) or no treatment in the umbilical site (no treatment - control group).

Intervention Type
Procedure/Surgery

Primary outcome measure
Recurrence rate at 1 year

Secondary outcome measures
1. Operative time
2. Morbidity (infection, seroma or chronic pain) at 1 month and 3 months

Overall study start date
01/01/2013

Completion date
30/12/2016

Eligibility

Key inclusion criteria

1. Patients undergoing surgery for symptomatic cholelitiasis
2. Age range 20-70 years
3. Male and female
4. American Society of Anesthesiology (ASA) classification of 3 or less
5. No co-morbidity cardiopulmonary, hepatic or renal impairment
6. Consent was given for surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100 patients: two groups of 50 patients

Key exclusion criteria
1. Patients with ASA higher than 3
2. Current malignant diseases
3. Proven mental illness or other circumstances that might compromise the patient's cooperation in addition to those who refused to give informed consent

Date of first enrolment
01/01/2015

Date of final enrolment
30/12/2016

Locations

Countries of recruitment
Spain

Study participating centre
La Vega Hospital
Murcia
Spain
30008

Sponsor information

Organisation
Medical Cañada (Spain)

Sponsor details
Calle Jubilo, S/N - Parcela 24 Nave C6
Poligono Industrial Oeste
San Ginés
Murcia
Spain
30820

Sponsor type
Industry

Website
www.medicalcanada.es

ROR
https://ror.org/011xgdn77

Funder(s)

Funder type
University/education

Funder Name
Universidad de Murcia

Alternative Name(s)
University of Murcia

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Spain

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
30/06/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date