

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/12/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/11/2015	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 cholelithiasis (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

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)

Prevention

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(s)

Recurrence rate at 1 year

Key secondary outcome(s)

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

Completion date

30/12/2016

Eligibility**Key inclusion criteria**

1. Patients undergoing surgery for symptomatic cholelithiasis
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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Data sharing statement to be made available at a later date