

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

<b>Submission date</b> 16/11/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/12/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/11/2015	<b>Condition category</b> 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  
moreno-egea@ono.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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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 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

**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](http://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