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Cost-effectiveness randomized study of laparoscopic versus open bilateral inguinal hernia repair

Submission date 20/02/2018	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 25/03/2018	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 23/03/2018	**Condition category** Surgery	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
An inguinal hernia is when part of the abdominal cavity protrudes through the inguinal canal. Inguinal hernia repair is one of the most widely performerd surgical procedure. Amongst the techniques used, the open Lichtenstein repair (OLR) is still the most widely performed. However, in the last decade there has been an increased interest in the laparoscopic approaches (keyhole surgery) for inguinal hernia repair, mainly represented as the trans-abdominal pre-peritoneal (TAPP) technique. This technique places a mesh to reinforce the abdominal wall. As described in recent studies, TAPP approach can be beneficial as it is less invasive and can be less painful /easier recovery. It is expected that these benefits would be more apparent in the treatment of bilateral inguinal hernias given the fact that both hernias are repaired through a single unified access. However, there are not enough studies in literature to support the potential benefits of the TAPP approach in bilateral inguinal hernias and none address its impact on the quality of life compared with OLR. The aim of this study is to evaluate if laparoscopic hernia repair is cost effective compared with open technique.

Who can participate?
Adults aged 18 and older who have an hernia and are requiring surgery.

What does the study involve?
Participants are allocated to one of two groups. Those in the first group undergo their surgery using the open technique. Those in the second group receive the laparoscopic TAPP technique. Participants are assessed after surgery to see how successful the surgery was, their quality of life and if their hernias have occurred.

What are the possible benefits and risks of participating?
Participants may benefit from having the TAPP technique used as this can be a less painful surgery and have a shorter recovery time in hospital. There are no direct risks.

Where is the study run from?
Sanchinarro University Hospital (Spain)

When is the study starting and how long is it expected to run for?
December 2012 to January 2017

Who is funding the study?
Investigator initiated and funded (Spain)

Who is the main contact?
Dr Benedetto Ielpo (Scientific)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
10203040

Study information

Scientific Title
Clinical and cost differences between laparoscopic TAPP versus traditional open Lichteinstein repair for bilateral inguinal hernia

Study objectives
The aim of this study is to evaluate if laparoscopic hernia repair is cost effective compared with open technique.

Ethics approval required
Old ethics approval format

Ethics approval(s)
HM Sanchinarro University Hospital, 01/12/2013

Study design
This is a clinical and cost-effectiveness analysis of a randomized clinical study comparing laparoscopic trans-abdominal pre-peritoneal (TAPP) technique with open Lichtenstein technique (OL) in bilateral inguinal hernia repair.

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Bilateral inguinal hernia repair

Interventions
This study was carried out in a private hospital in Madrid (Spain) at the General Surgery Department of Sanchinarro University Hospital recruiting patients from March 2013. Patients (aged over 18 years), with primary, bilateral inguinal hernias assessed by ultrasound are included. The patient demographic data recorded are: age, gender, Body Mass Index (BMI), American Society of Anaesthesiology (ASA score), comorbidities and size of hernia according to the European Hernia Society (EHS) classification (Grade I: 1.5 cm, Grade II: 1.5–3 cm, Grade III: >3 cm) (8).

Participants are randomised using a simple randomization with a computer program and divided into two groups according to the surgical approach elected by the computer program: laparoscopic trans-abdominal pre-peritoneal (TAPP) technique with open Lichtenstein technique (OL).

Open Technique (OL):
OL is performed by all surgeons according to the standard Lichtenstein open tension-free technique as described recently by Amid where ilioinguinal and iliohypogastric nerves are usually preserved. No local anesthetic is infiltrated.

Laparoscopic TAPP technique:
This procedure is performed under general anaesthesia. Pneumoperitoneum is established with a Veress needle in the left subcostal space. .The peritoneum is incised and the hernia sac is than isolated and reduced freeing the spermatic cord. Finally, two polypropylene meshes (Prim) of almost 15x10 cm are rolled and introduced in the abdominal cavity bilaterally in both preperitoneal spaces. A unique metal staple is used to secure the mesh to each Cooper ligament (CapSureTM, Bard). The peritoneal flap is than closed using 3 or 4 metal staples for each side.

Participants undergo their surgery according to the protocols in each of their groups. Participants are followed up after surgery to assess their clinical outcomes, quality of life and recurrences of hernia.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Clinical outcomes are measured as:
1.1. Time of surgery has been defined since the induction of general anaesthesia and recorded up to the close of the skin
1.2. Length of post-operative stay as well as postoperative complications have been prospectively recorded
1.3. Seroma is defined when it is symptomatic (pain, discomfort, etc..) and that tends to persist for long periods from surgery (> 1 month) and which often requires an interventional

therapeutic approach (needle aspiration)
1.4. Postoperative pain was determinated at first and 7th day after surgery and at 2, 6 and 12 months, using the standardized 0-10 visual analgesic scale (VAS). After the discharge, it is gathered in outpatient clinic
1.5. Chronic pain was recorded and defined if it is lasting no less then 3 months after the hernia repair and which requires some analgesic drug
1.6. Number of outpatient surgical visits were also recorded as well as re admission or emergency visit without admission
2. Quality of life was assessed with the medical outcomes study SF-36 questionnaire (Spanish form) preoperatively and at 2, 6 and 12 months after surgery
3. Cost effectiveness is measured using incremental cost-effectiveness ratios (ICERs) at 1 years from surgery. The Institute of Validation of Efficacy Clinic (IVEC) of the HM Hospitals group is responsible for capturing costs ascribed to each patient's treatment. The total direct hospital costs of care were recorded under the patient's unique medical record number.

Key secondary outcome(s))
Recurrences are measured using outpatient visits after six months

Completion date
10/01/2017

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Primary, bilateral inguinal hernias assessed by ultrasound

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Recurrent hernia

Date of first enrolment
01/01/2013

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
Spain

Study participating centre
Sanchinarro University Hospital
Madrid
Spain
28050

Sponsor information

Organisation
Sanchinarro University Hospital

ROR
https://ror.org/04jep6391

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Emilio Vicente (Head of the General Surgical Department) at emilvic@bitmailer.net.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	Participant information sheet				

Participant information sheet	11/11/2025	11/11/2025	No	Yes