ISRCTN47111213 https://doi.org/10.1186/ISRCTN47111213

Comparison of one layer vs. two layer Modified Kugel mesh for inguinal herniorrhaphy

Submission date 17/03/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/03/2017	**Overall study status** Completed	
Last Edited 16/05/2023	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
A hernia occurs when an internal organ pushes through the muscle or tissue that holds it in place. It usually develops on the chest or hips area and can cause swelling or a lump. A hernia requires surgery in order to be repaired. Surgery can be done laparoscopically which is less invasive surgery that uses a small keyhole incision and cameras to repair the hernia. Mesh can be used to reinforce the tissue to make sure that the hernia does not occur again. There are different types of mesh and different places that it can be placed inside the body. One of the most popular places to put the mesh is in the pre-peritoneal space (part of the abdominal wall) to cover any weaknesses found there. In order to prevent hernias from returning, another optional on-lay mesh layer can also be placed in the inguinal canal (a passage in the abdominal wall). It is possible that the additional layer of mesh could help prevent future hernias but it also could just create future problems. The aim of this study is to evaluate how well the additional mesh layer is at preventing hernias when compared to just a single layer of mesh and to see if there are any detrimental effects of using the optional on-lay mesh layer.

Who can participate?
Patients (all ages) undergoing hernia surgery

What does the study involve?
Participants are randomly allocated to one of two groups. All participants undergo the standard surgical procedure for open mesh hernia repair. Those in group one have their hernia repaired using a single mesh layer placed in the space in front of to the peritoneum (pre-peritoneal) and those in group two receive an additional layer placed in the inguinal canal as well. Participants stay in the hospital for one or two days post-surgery to recover (as to the standard level of care). Participants attend an appointment with their surgeon seven days after the surgery to discuss any issues they are having. Participants are then followed up with the research team by telephone interviews done at one, three, six and 12 months post-surgery to assess pain and to see if the hernia returned.

What are the possible benefits and risks of participating?
Participants may benefit from less pain post-surgery. Participants in group two are at risk of experiencing more pain post-surgery.

Where is the study run from?
Changhua Christian Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
January 2014 to January 2017.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Pao-Hwa Chen

Contact information

Type(s)
Public

Contact name
Dr Pao-Hwa, Walt Chen

ORCID ID
http://orcid.org/0000-0003-4623-1800

Contact details
Changhua Christian Hospital
135 Nanxiao Street
Changhua City
Taiwan
500

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IRB-140312

Study information

Scientific Title
Long-term complication following trans-inguinal pre-peritoneal Modified Kugel mesh herniorrhaphy: A single blind prospective randomized controlled trial

Study objectives

A single layer mesh in the preperitoneal space is sufficient to prevent recurrence and the use of second layer in the inguinal canal is not necessary.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Changhua Christian Hospital Institutional Review Board, 23/05/2014, ref: #140312

Study design
Single blind prospective randomized controlled 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
Inguinal hernia repair using open method

Interventions
Participating are randomised on a 1:1 basis. Participants are randomly allocated based on a numbering system to being in group one or group two. Surgery is scheduled for one week after clinical visit. All fees incurred are paid by the National Health Care Insurance or patients' own insurance

Group one: Participants undergo the open hernia repair surgical procedure to repair the hernia and then they receive the single layer pre-peritoneal Modified Kugel (MK) mesh placement in the per-peritoneal space. This is done through a 3-4 cm inguinal incision.

Group two: Participants receive the same procedure as Group one patients but also receive the additional on-lay in the inguinal canal. This is also done through a 3-4 cm inguinal incision.

The surgical approach in each group is feasible and there is no standard of treatment, however those in group one will act as a control in order to compare their outcomes with those in group two to see if an optional on-lay has any benefits than the one layer mesh.

After the surgery, a separate research personnel (not the surgeon whom performed the surgery) follows-up all the patients for at least one year after surgery at set intervals (seven days, one,

three, six and 12 months) with a set of questionnaires. The data is the passed to another research personnel for data analysis.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Recurrence is measured using a clinical visit at day seven and through questionnaires via telephone interviews at one, three, six and 12 months
2. Pain is measured using a clinical visit at post-OP day seven and through questionnaires via telephone interviews at one, three, six and 12 months
3. Inguinal nerve neuropathy is measured using a clinical visit at day seven and through questionnaires via telephone interviews at one, three, six and 12 months

Secondary outcome measures
Foreign body sensation are measured using a clinical visit at day seven and through questionnaires via telephone interviews at one, three, six and 12 months.

Overall study start date
15/01/2014

Completion date
30/01/2017

Eligibility

Key inclusion criteria
1. Any patient undergoing elective inguinal herniorrhaphy at Changhua Christian Hospital
2. All ages and genders
3. Any patient with clinical presentation of inguinal hernia is eligible for our study

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
100 patients undergoing elective inguinal repair

Key exclusion criteria
1. Recurrent hernias
2. Hernia defects larger than the Posiflex® memory ring diameter
3. Refusal to participate in the randomizing protocol

Date of first enrolment
27/05/2014

Date of final enrolment
30/08/2016

Locations

Countries of recruitment
Taiwan

Study participating centre
Changhua Christian Hospital
135 Nanxiao Street
Changhua City
Changhua County
Taiwan
500

Sponsor information

Organisation
Changhua Christian Hospital

Sponsor details
135 Nanxiao Street
Changhua City
Taiwan
500

Sponsor type
Hospital/treatment centre

Website
http://www.cch.org.tw/home.aspx

ROR
https://ror.org/05d9dtr71

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/01/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Pao-Hwa (Walt) Chen at 149690@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/09/2022	16/05/2023	Yes	No