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A comparison of different surgical techniques for incisional hernia treatment

Submission date
06/09/2012

Recruitment status
No longer recruiting

Registration date
02/11/2012

Overall study status
Completed

Last Edited
27/11/2015

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Incisional hernias occur when tissue pokes through a surgical wound in the abdomen that has not fully healed. Laparoscopic (keyhole) surgery has better results in terms of pain, quality of life, and time taken to return to full activity, compared with other types of surgery. However, there are many cases when laparoscopic repair is impossible to perform (e.g., large hernia, other illness). The aim of this study is to compare the results of two different incisional hernia repair techniques: sublay and laparoscopic surgery.

Who can participate?
Patients 18 aged 75 with a midline incisional hernia undergoing surgical hernia repair.

What does the study involve?
Participants are randomly allocated to undergo either sublay or laparoscopic surgery.

What are the possible benefits and risks of participating?
The risks include wound complications, bowel injury, and postoperative pneumonia.

Where is the study run from?
Lithuanian University of Health Sciences (Lithuania).

When is the study starting and how long is it expected to run for?
April 2011 to April 2016.

Who is funding the study?
Lithuanian University of Health Sciences (Lithuania).

Who is the main contact?
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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
P1-73

Study information

Scientific Title
A comparison of sublay versus laparoscopic surgical techniques for incisional hernia treatment: a prospective randomized study

Study objectives
The results of sublay and laparoscopic surgery techniques of incisional hernia treatment are similar.

Ethics approval required
Old ethics approval format

Ethics approval(s)
08/03/2011, ref: P1-73

Study design
Prospective randomized controlled study

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
Surgery for incisional hernia

Interventions
Surgery (hernia repair operations)

Two groups:
1. Sublay technique
2. Laparoscopic technique

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Recurrence rate

Secondary outcome measures
1. Postoperative pain
2. Postoperative complications
3. Qualite of life
4. Time of return to full physical activity

Overall study start date
01/04/2011

Completion date
01/04/2016

Eligibility

Key inclusion criteria
1. Patients with midline incisional hernia undergoing surgical hernia repair
2. Age of patients 18 to 75 years

3. No mental and nervous disorders
4. Patients provide written informed consent to participate in the prospective study before surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
100 (50 in each group)

Key exclusion criteria
1. Patients older than 75 years
2. Incarcerated incisional hernia
3. Urgent surgery of the patients (peritonitis, acute bleeding, ileus et ct.) with incisional hernia
4. Patients with mental and nervous disorders
5. Pregnant women with incisional hernia
6. Patients participation in other clinical study
7. Patients resign to participate in the clinical study

Date of first enrolment
01/04/2011

Date of final enrolment
01/04/2016

Locations

Countries of recruitment
Lithuania

Study participating centre
Lithuanian University of Health Sciences
Kaunas
Lithuania
LT 50009

Sponsor information

Organisation
Lithuanian University of Health Sciences (Lithuania)

Sponsor details
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Sponsor type
University/education

Website
http://www.kmuk.lt/

ROR
https://ror.org/0069bkg23

Funder(s)

Funder type
University/education

Funder Name
Lithuanian University of Health Sciences (Lithuania)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration