

A comparison of different surgical techniques for incisional hernia treatment

Submission date 06/09/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/11/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/11/2015	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

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Additional identifiers**Protocol serial number**

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

Study type(s)

Treatment

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(s)

Recurrence rate

Key secondary outcome(s)

1. Postoperative pain
2. Postoperative complications
3. Quality of life
4. Time of return to full physical activity

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

75 years

Sex

All

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)

ROR

<https://ror.org/0069bkg23>

Funder(s)**Funder type**

University/education

Funder Name

Lithuanian University of Health Sciences (Lithuania)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration