A comparison of different surgical techniques for incisional hernia treatment

Submission date 06/09/2012	Recruitment status No longer recruiting	Prospectively registeredProtocol	
Registration date 02/11/2012	Overall study status Completed	Statistical analysis planResultsIndividual participant dataRecord updated in last year	
Last Edited 27/11/2015	Condition category Surgery		
not fully healed. Lap life, and time taken there are many case illness). The aim of t	idy aims ccur when tissue pokes paroscopic (keyhole) su to return to full activit es when laparoscopic re	through a surgical wound in the abdomen that has rgery has better results in terms of pain, quality of y, compared with other types of surgery. However, epair is impossible to perform (e.g., large hernia, other e the results of two different incisional hernia repair Ty.	
Who can participate Patients 18 aged 75		al hernia undergoing surgical hernia repair.	
What does the stud Participants are ran		ergo either sublay or laparoscopic surgery.	
-	ole benefits and risks of ound complications, boo	participating? wel injury, and postoperative pneumonia.	
Where is the study i Lithuanian Universil	run from? cy of Health Sciences (L	ithuania).	
When is the study s April 2011 to April 2	tarting and how long is 2016.	it expected to run for?	
Who is funding the Lithuanian Universit	study? cy of Health Sciences (L	ithuania).	
Who is the main con	ntact?		

Contact information

linasvenclauskasg@yahoo.com

Linas Venclauskas

Type(s)

Scientific

Contact name

Prof Mindaugas Kiudelis

Contact details

Lithuanian University of Health Sciences Department of Surgery Eiveniu str. 2 Kaunas Lithuania LT 50009

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minkiud@yahoo.com

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

Department of Surgery Eiveniu str. 2 Kaunas Lithuania LT 50009

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chirurgijosklinika@kaunoklinikos.lt

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