

Optimisation of incision hernia surgery treatment

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| Submission date 19/11/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 04/03/2008 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 05/03/2008 | Condition category Digestive System | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Linas Venclauskas

Contact details
Eiveniu str. 2
Kaunas
Lithuania
LT50009

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
73/2007

Study information

Scientific Title

Study objectives

1. Open mesh repair hernia surgery is better than suture repair hernia surgery of incision hernia treatment
2. The recurrence rate using suture hernia repair technique is much higher than mesh repair technique
3. The recovering time to the normal physical activity after surgery is faster, quality of life is better using mesh repair with sublay technique than mesh repair with onlay technique or suture repair technique of the incision hernia treatment

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from Kaunas Biomedical Research Ethics Committee on the 5th June 2007 (ref: BE-2-41).

Study design

Blinded, randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Hernia

Interventions

Three groups:

1. Keel technique
2. Onlay technique
3. Sublay technique

The follow up period is 2 weeks, 1, 3, 6 and 12 months after surgery. Surgery, blood gas analysis and intra-abdominal pressure investigation before and after operation.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Recurrence rate, measured at 2 weeks, 1, 3, 6 and 12 months after surgery
2. Quality of life, measured using the 36-item Short Form health survey version 2 (SF-36 v2) at 2 weeks, 1, 3, 6 and 12 months after surgery

Secondary outcome measures

1. Postoperative complications, measured at 2 weeks, 1, 3, 6 and 12 months after surgery
2. Change of the blood gas and intra-abdominal pressure, measured before and after surgery
3. Recovering time to the normal physical activity after surgery, measured at 2 weeks, 1, 3, 6 and 12 months after surgery

Overall study start date

01/07/2007

Completion date

01/07/2008

Eligibility

Key inclusion criteria

All 18 - 80 years old patients with incision hernia, who will be operated and agree to participate in this clinical trial.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50 patients in each group, 150 patients in all

Key exclusion criteria

1. Patients older than 80 years
2. Incarcerated incision hernia
3. Mental patients with incision hernia
4. Pregnant women with incision hernia
5. Patients with incision hernia do not agree to participate in this clinical trial

Date of first enrolment

01/07/2007

Date of final enrolment

01/07/2008

Locations

Countries of recruitment

Lithuania

Study participating centre

Eiveniu str. 2

Kaunas

Lithuania

LT50009

Sponsor information

Organisation

Kaunas Medical University Hospital (Lithuania) - Department of Surgery

Sponsor details

Eiveniu str. 2

Kaunas

Lithuania

LT50009

Sponsor type

Hospital/treatment centre

Website

<http://www.kmu.lt/>

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Kaunas Medical University Hospital (Lithuania) - Department of Surgery

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