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Optimisation of incision hernia surgery treatment

Submission date	Recruitment status	[ ] Prospectively registered
19/11/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/03/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/03/2008	Digestive System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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