ISRCTN11190874 https://doi.org/10.1186/ISRCTN11190874

Investigating the effect of intra-operative infiltration with local anaesthesia on the development of chronic postoperative pain after inguinal hernia repair

Submission date
14/05/2007

Registration date
16/07/2007

Last Edited
01/02/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Digestive System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
NCT00484731

Secondary identifying numbers
585

Study information

Scientific Title
Effect of intraoperative infiltration with local anaesthesia on the development of chronic pain after inguinal hernia repair: a randomized, triple-blinded, placebo-controlled trial.

Study objectives
We hypothesize that intra-operative infiltration with local anaesthesia (bupivacain) will lead to 50% reduction of the occurrence of chronic postoperative pain after inguinal hernia repair.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethical Committee of the Canton Lucerne, approved on 1 May 2006, amended on 26 February 2007 (ref: 585)

Study design
A randomized, placebo-controlled, triple-blinded and group sequential study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Inguinal hernia

Interventions
Intervention group: Intraoperative injection of 20 ml bupivacain (0.25%) during inguinal hernia repair
Control group: Intraoperative injection of saline during inguinal hernia repair

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Occurrence of chronic pain (persistent pain at three-month follow-up measured by Visual Analogue Scale and Pain Matcher®) in the operated groin region.

Secondary outcome measures
The following will be measured at 1-, 3- and 12-month follow-up:
1. Level of pain: Pain Matcher®, VAS, areas of hyperalgesia, hypaesthesia
2. Hospitalization: Length of stay (days), American Society of Anesthesiologists (ASA) Classification, beginning of mobilisation (days)
3. Function: Return to work or normal activity (days and %), Quality of life (36-item Short Form health survey [SF-36])

Overall study start date
01/07/2006

Completion date
01/08/2008

Eligibility

Key inclusion criteria
1. 18 years or older
2. Primary or recurrent single or double sided symptomatic but not incarcerated inguinal hernias with an elective hernia repair
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
264

Key exclusion criteria
1. Patients with legal incompetence
2. Pregnant and nursing women
3. Presence or history of active malignancy or systemic diseases
4. Under immunosuppressive treatment
5. Systemic or severe local inflammation or infection
6. Wound healing disorders
7. Physical or mental incapacity, which makes it impossible to obtain informed consent
8. Patients with pacemakers or other implanted electrical devices (as pacemakers interfere with

the electrical stimulation of the Pain Matcher® and vice versa)
9. Other types of hernia (e.g. umbilical hernia)

Date of first enrolment
01/07/2006

Date of final enrolment
01/08/2008

Locations

Countries of recruitment
Switzerland

Study participating centre
Spitalstrasse
Luzern
Switzerland
6000

Sponsor information

Organisation
Lucerne Cantonal Hospital (Switzerland)

Sponsor details
Spitalstrasse
Luzern
Switzerland
6000
+41 41 205 11 11
info@ksl.ch

Sponsor type
Hospital/treatment centre

Website
http://www.ksl.ch/GSD/KSL/Web/KSLwww.nsf/web/default

ROR
https://ror.org/02zk3am42

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Lucerne Cantonal Hospital (Kantonsspital Luzern) (Switzerland)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/11/2007	01/02/2019	Yes	No
Results article	results	01/01/2015	01/02/2019	Yes	No