

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/07/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/02/2019	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

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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