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	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/07/2007	**Overall study status** Completed	
Last Edited 01/02/2019	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jürg Metzger

Contact details
Spitalstrasse
Luzern
Switzerland
6000
-
juerg.metzger@ksl.ch

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00484731

Protocol serial number
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

Study type(s)
Not Specified

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

Key secondary outcome(s))
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])

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

ROR
https://ror.org/02zk3am42

Funder(s)

Funder type
Hospital/treatment centre

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

Results and Publications

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?
Results article	results	01/01/2015	01/02/2019	Yes	No
Protocol article	protocol	06/11/2007	01/02/2019	Yes	No