

TAP-study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25473

Source

Nationaal Trial Register

Health condition

Elective mentally competent surgical patients for open inguinal hernia repair in daytime surgery

De onderzoekspopulatie bestaat uit wilsbekwame proefpersonen ouder dan 18 jaar die zich op de preoperatieve screening van de polikliniek van de afdeling anesthesiologie in het Westfriesgasthuis presenteren voor een operatieve correctie van een liesbreuk volgens Lichtenstein en die voldoen aan de in en exclusie criteria zoals hieronder vermeld. De proefpersonen worden geïnccludeerd na informed consent.

Sponsors and support

Primary sponsor: Westfries medical center Hoorn

Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

Analyse difference in numeric rating scale between the 2 groups until 48 hours after the operation

Secondary outcome

Time to first use of intravenous morphine

Total amount of titrated morphine

Use of tramadol at home

Patient satisfaction

The incidence of nausea and vomiting

Study description

Background summary

Hernia inguinal repair is the most common operation performed by general surgeons in the Netherlands. One of the most common complications after hernia repair is postoperative and chronic pain. Postoperative pain is an expected but undesirable effect after an operation, which can result in a prolonged hospital stay or longer time to return to full normal daily activities. There are indications that an insufficient treatment of postoperative pain is a risk factor for persistent or chronic pain after open hernia repair. The objective of this study is to determine, whether the use of an perioperative echo guided unilateral TAP block has a superior effect on postoperative pain after open hernia inguinal repair compared to wound infiltration with a long acting local anesthetic. There will be no further analysis in this study regarding the relation of open hernia repair and chronic pain

Study objective

Is a transversus abdominis plane block more effective regarding postoperative pain than perioperative wound infiltration with a long acting local anesthetic for a group of patients for open inguinal hernia repair

Study design

NRS rating scale 48 hours post surgery

Leiden Perioperative care Patient Satisfaction questionnaire (LPPSq)

Intervention

Procedure/surgery: TAP block

2 groups, group A a TAP block with 20ml of levobupivacaine 0,5% and subcutaneous wound

infiltration with 20ml sodium chloride (to blind patient and physician) and group B, TAP block with 20ml sodium chloride and subcutaneous wound infiltration with 20ml levobupivacaine 0,5% (to blind patient and physician)

Contacts

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Eligibility criteria

Inclusion criteria

Male patients, Age between 18-80 years (18-80 jaar), mentally competent, American Society of Anesthesiologists (ASA) class score 1-3, elective surgery, Body Mass Index (BMI) between 20 en 35.

Exclusion criteria

Body Mass Index (BMI) >35, fever, coagulation disorders (PT>13 sec en APPT >32 sec), renal insufficiency(eGFR< 50 ml/min), serious hepatic impairment(albumine <30g/L and or INR>2), woundinfection close to puncture site, preoperative use of analgetics, hypersensitivity for Levobupivacaine

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	11-12-2014
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion	
Date:	18-11-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42102
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5386
NTR-old	NTR5487
CCMO	NL49853.094.14
OMON	NL-OMON42102

Study results