A pilot study on the effectiveness of the echoguided Transversus Abdominis Plane block during inguinal hernia repair surgery.

Published: 03-05-2012
Last updated: 28-04-2024

-The objective of this study is to determine, whether the use of an perioperative echo guided unilateral TAP block has an superior effect on postoperative pain after open hernia inguinal repair compared to wound infiltration with a long acting local...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Soft tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON37527

Source
ToetsingOnline

Brief title
pilot study the effectiveness of an TAP-block for inguinal hernia repair

Condition

- Soft tissue therapeutic procedures

Synonym
post-operative pain after inguinal hernia repair

Research involving
Human

Sponsors and support

Primary sponsor: Westfries Gasthuis

Source(s) of monetary or material Support: vakgroep anaesthesie

Intervention

Keyword: inguinal hernia, local anaesthetic, pain, TAP-block

Outcome measures

Primary outcome

-Primary objective is to analyse, differences in pain scores between the 2

groups until 48 hours after the operation.

Secondary outcome

-Secondary objectives are; time to to first use of intravenous Morfine, the

total amount of titrated postoperative Morfine, use of Tramadol at home,

patient satisfaction en 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. On 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 an prolonged hospital stay or longer time to return to full normal daily activities. There are indications that an insufficiant treatment of postoperative pain is a risk factor for persistant or chronic pain after open inguinal hernia repair. Chronic pain is not uncommon after hernia repair, with an incidence of 11%.

Study objective

-The objective of this study is to determine, whether the use of an perioperative echo guided unilateral TAP block has an 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 incidence of open hernia inguinal repair and chronic pain.

Study design

- An prospective double blinded randomised trial.

Intervention

-Perioperative echo guided TAP block.

Study burden and risks

-The use of the echo-guided unilateral TAP block is standard hospital care.

Contacts

Public
Westfries Gasthuis

Maelsonstraat 3 3
Hoorn 1624NP
NL
Scientific
Westfries Gasthuis

Maelsonstraat 3 3
Hoorn 1624NP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age between 18 and 80 year, competent, elective surgical treatment, Body Mass Index (BMI between 20-35,

Exclusion criteria

fever, a coagulation disorder, patiënts with kidney and liverfaillure, an infection at the place where the puncture place, preoperative use of narcotic and NSAID's,

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-09-2012
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Chirocaine
Generic name:	levobupivacaine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	03-05-2012
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	18-09-2012
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2012-001837-15-NL
CCMO	NL40460.094.12