

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

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-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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Soft tissue therapeutic procedures
<b>Study type</b>	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 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. 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 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 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 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

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NL

### Scientific

Westfries Gasthuis

Maelsonstraat 3 3  
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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, patients with kidney and liver failure, 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