# Local infiltration with anesthetics vs placebo in patients with elective total hip replacement (thr) in fast-track protocol

Published: 14-01-2014
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Primary objective: The primary purpose of the research is to determine the difference in pain experience during rest, measured by means of an 11-point Numerical Rating Scale (NRS), between peroperatieve Local infiltration with Analgesics (LIA) vs....

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Joint disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON41707

**Source**
ToetsingOnline

**Brief title**
nvt

### Condition

- Joint disorders

**Synonym**
new hip, pain management

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Spaarne Ziekenhuis
**Source(s) of monetary or material Support:** eigen stimuleringsfonds

## Intervention

**Keyword:** fast-track, lia, total Hip replacement

## Outcome measures

### Primary outcome

The primary endpoint is the NRS pain score 24 hours postoperatively at rest

### Secondary outcome

Secondary endpoints are the-NRS scores for pain (from 24 hours) to 48 hours

postoperatively

-HOOS (pre OK and 6 WKS post)

-SF12 (pre OK and 6 WKS post)

-Oxford Hip score (pre OK and 6 WKS post)

-length of stay

-Presence of nausea, vomiting, bladder retention

-Complications

-Use analgesics: PCA-use/opiates

- NRS pain during rest and mobilization till 48 hours postoepratively

# Study description

### Background summary

Approximately 23,000 hip prostheses are placed annualy in the Netherlands in patients suffering from symptomatic coxarthrosis. The purpose of this operation is to improve the quality of life by releaving joint related hip pain and increasing mobility. Early mobilization of patients after surgery is important to prevent complications such as a urinary tract infection, pneumonia, deep vein thrombosis and pressure ulcers. The multidisciplinary multimodal Fast-Track protocol is based on the fact that people who fast mobile are less likely to develope these complications. Because post operative pain interferes

with an early mobilisation, local infiltration anesthesia per-operatively (LIA) is an important part of the Fast track protocol. This aims to reduce the pain around the operation area. When placing total knee prostheses administering LIA is proven effective, however the utility is as yet not yet shown when placing a THP. Some studies describe reduction of pain and a shortened hospital stay after administering LIA in the wound edges of the surgical area, but these results could not be repeated in another study.

Administering LIA surrounding the nerves in the surgery area has not been investigated previously. Cutaneus femoralis lateralis and the facial nerve nervus subcostalis innervate the skin at the level of the hip.Theoretically infiltrating the subcutaneous area of this nerve sprigs around the spina ilica superior anterior results in conduction anesthesia of skin at the location of the surgical area. The purpose of the present study is to show that local infiltration anesthesia with ropivacaine in patients with THP in the fast-track protocol leads to better pain reduction than placebo 24 hours after surgery.

**Study objective**

Primary objective:
The primary purpose of the research is to determine the difference in pain experience during rest, measured by means of an 11-point Numerical Rating Scale (NRS), between peroperatieve Local infiltration with Analgesics (LIA) vs. placebo, 24 hours postoperatively in patients with total hip replacement in the fast-track protocol.

Secondary objective: a secondary objective of the study is to determine the difference in secondary outcome measures between peroperatieve Local infiltration with Analgesics (LIA) vs. placebo, postoperatively in patients with total hip replacement in the fast-track protocol.

The secondary outcomes are:
-HOOS (pre OK and 6 WKS post)
-SF12 (Pre OK and 6 WKS post)
-Oxford Hip score (BL and 6 WKS post)
-Length of stay
-Presence of nausea, vomiting, bladder retention
-Complications
-Use analgesics: PCA-use/opiates
- NRS for pain during rest and mobilization till 48 hours postoperatively

**Study design**

This study concerns a single-center, placebo-controlled, double-blind randomized study to investigate the postoperative pain in patients with total hip replacement (thr) in a fast-track protocol.

Clinic: Department of Orthopaedics in the Spaarne Ziekenhuis

**Intervention**

In our study, the post-operative pain in patients who have undergone a THP examined. The subjects are divided into two groups.
Patients in Group 1 get an infiltration with ropivacaine pre-operatively 3.75 mg/kg (0.5 ml/kg body weight).
Patients in Group 2 get a pre-operatively infiltration with NaCl 0.9% (0.5 ml/kg body weight)

**Study burden and risks**

Ropivacaine is an anesthetic which is used for local anesthesia. The administration takes place via the cutaneus femoralis lateralis and the facial nerve nervus subcostalis . The maximum cumulative 24-hour dosage, which is well tolerated is 675 mg (source: ChemSpider). In our protocol patients get 3.75 mg/kg, which is well below this dose ropivacine. Side effects are rare and usually the result of overdose mistakenly given by intravascular injections (hypotension, nausea > 10%; headache, paresthesia, dizziness, bradycardia, tachycardia, hypertension, vomiting, urinary retention, temperature rise, muscle stiffness, backache > 1%). To prevent this is before infiltration first the needle is aspirated in order to exclude intravascular placement. Subcutaneous administration of NaCl does not bring any increased risk to the patient.

The parameters that are evaluated are not a burden for the patients because these data is structural collected in all patients. No additional investigations and/or actions will take place

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

-in writing given informed consent ;-over 18 years of age ;- operation indication: primary coxarthrosis ;-Dutch speaking and understanding ;-Spinal anaesthesia ;-patients who go home after surgery (secondary outcome length of stay)

## Exclusion criteria

-Patients who within 12 months prior to the surgery were opioid-dependent. ;-malignancies. ;-Patients with co-morbidities which may affect the possible pain perception (in the prehistory: CVA or a psychiatric disorder). ;-Patients with allergies to ropivacaine ;-ASA 3-4 ;-Patients with a peroperatieve complication occurs which interferes with the normal mobilization and pain experience (fractures, vascular/nerve injury

# Study design

## Design

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

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|---|---|
| Control: | Placebo |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 21-07-2014 |
| Enrollment: | 160 |
| Type: | Actual |

### Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |
| Brand name: | Natriumchlorid 0,9% |
| Generic name: | nacl 0,9% |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | Ropivacaine |
| Generic name: | hydrochlorid |
| Registration: | Yes - NL intended use |

## Ethics review

Approved WMO

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|---|---|
| Date: | 14-01-2014 |
| Application type: | First submission |
| Review commission: | METC Noord-Holland (Alkmaar) |

Approved WMO

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|---|---|
| Date: | 27-03-2014 |
| Application type: | First submission |
| Review commission: | METC Noord-Holland (Alkmaar) |

Approved WMO

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|---|---|
| Date: | 30-09-2015 |
| Application type: | Amendment |
| 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 | EUCTR2013-004031-71-NL |
| CCMO | NL45740.094.14 |