

# The effect of extra local anaesthesia during total hip arthroplasty

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<b>Registration date</b> 25/07/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/01/2020	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Arthritis is a condition that causes joints to become painful and stiff. Hip osteoarthritis can be treated with a total hip arthroplasty (hip replacement surgery), where the damaged hip joint is replaced with an artificial implant. During and after the surgery, patients receive pain medication to be pain free after surgery and to be able to rehabilitate after surgery. Local anaesthesia during surgery might further alleviate pain after surgery. Patients might be able to rehabilitate more easy and faster. Patients might need less medication and might be discharged earlier from the hospital. There are a variety of different types of anaesthesia that can be used such as topivacaine and ropivacaine. The aim of this study is to examine the effect of extra local anaesthesia during total hip arthroplasty.

### Who can participate?

Adults aged 18 and older who require a total hip replacement

### What does the study involve?

Participants are randomly allocated to one of three groups. Those in the first group receive an antegrade infiltration that contains topivacaine/epinephrine. Those in the second group receive a reversed infiltration with ropivacaine/epinephrine. Those in the last group receive a placebo (a dummy) medication containing saline (salt water). Participants are asked to rate their pain, nausea and vomiting after surgery.

### What are the possible benefits and risks of participating?

Participants may benefit from a reduction in pain. Participants in the placebo group may experience more pain than the other groups. All participants receive rescue medication when the standard pain medication is insufficient.

### Where is the study run from?

Reinier de Graaf Hospital (Netherlands)

### When is the study starting and how long is it expected to run for?

June 2011 to January 2018

Who is funding the study?  
Reinier de Graaf Hospital (Netherlands)

Who is the main contact?  
Miss Nina Mathijssen  
N.Mathijssen@rdgg.nl

## Contact information

**Type(s)**  
Public

**Contact name**  
Miss Nina Mathijssen

**Contact details**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
2012-000989-37

**Protocol serial number**  
2012-002-M

## Study information

**Scientific Title**  
Local infiltration anaesthesia in total hip arthroplasty by anterior supine intermuscular approach

**Study objectives**

1. Patients administered perioperative reversed local infiltration of ropivacaine will have lower pain scores, a faster rehabilitation, and lower cumulative consumption of (opioid-) pain medication postoperative, when compared to patients administered antegrade local infiltration of ropivacaine or saline.
2. Patients administered perioperative antegrade local infiltration of ropivacaine will have lower pain scores, a faster rehabilitation, and lower cumulative consumption of (opioid-) pain medication postoperative, when compared to patients administered antegrade local infiltration of saline.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

## **Study design**

Interventional randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Osteoarthritis of the hip

## **Interventions**

This study is a randomised, controlled blind (for the patient) trial, comparing the outcomes in patients with coxarthrosis after THA with the ASI technique. Participants are randomised in an antegrade infiltration group with ropivacaine, a reversed infiltration group with ropivacaine and an antegrade placebo infiltration group.

Participants are randomised to the following groups using opaque sealed envelopes on the operating room:

Group 1 Antegrade: Participants receive an antegrade infiltration that contains ropivacaine /epinephrine as a dose of 1:100.000 120 ml

Group 2 Reversed: Participants receive a reversed infiltration with ropivacaine/epinephrine as a dose of 1:100.000 120 ml

Group 3 Antegrade placebo: Participants receive an antegrade placebo that contains saline with a dose of 120 ml

Participants are asked if they experienced pain (and how much), nausea and/or vomiting after surgery. The study ends for each participant when they are discharged from the hospital.

## **Intervention Type**

Other

## **Primary outcome(s)**

Pain is measured using the numerical rating scale (NRS) for pain at one, four and eight hours after surgery, in rest, while and direct after mobilization, starting at four-six hours after surgery.

## **Key secondary outcome(s)**

1. Pain is measured using the numerical rating scale (NRS) for pain at day two and until the day of discharge at two moments (morning and afternoon). Also during and direct after mobilisation, pain is measured with NRS for pain.
2. Preoperative pain is measured during postoperative screening with NRS for pain, the neuropathic pain diagnostic questionnaire (DN4), and Amsterdam Preoperative Anxiety and Information Scale (APAIS) for anxiety and information requirements
3. Postoperative vomiting and nausea is asked at the moments the NRS is scored
4. Cumulative consumption of opioid medication and pain medication is scored
5. Length of hospital stay by amount of nights is counted at hospital discharge

## **Completion date**

01/01/2018

## Eligibility

### Key inclusion criteria

1. Patients who are diagnosed for a total hip arthroplasty with osteoarthritis
2. Patients aged 18 years and older
3. Patients willing to participate
4. ASA I and II

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### Key exclusion criteria

1. Patients unwilling to participate
2. Mentally retarded
3. Neurological conditions potentially influence pain perception
4. Psychiatric conditions potentially influence pain perception
5. ASA III, IV
6. Cardiovascular impairment in the present or in the past

### Date of first enrolment

06/11/2012

### Date of final enrolment

09/01/2014

## Locations

### Countries of recruitment

United Kingdom

Netherlands

### Study participating centre

**Reinier de Graaf Hospital**  
Reinier de Graafweg 5  
Delft  
Netherlands  
2625AD

## Sponsor information

### Organisation

Reinier de Graaf Groep, department of orthopaedics

### ROR

<https://ror.org/00wkhef66>

## Funder(s)

### Funder type

Government

### Funder Name

Reinier de Graaf Groep

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Nina Mathijssen (N.Mathijssen@rdgg.nl).

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	24/08/2017		Yes	No