Local Infiltration Anaesthesia in Total Hip Arthroplasty by Anterior Supine Intermuscular Approach.

No registrations found.

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

Summary

ID

NL-OMON23714

Source
NTR

Brief title
LIA in THA-ASI

Health condition

postoperative pain after hip replacement THA by Aterior Supine Intermuscular Approach (ASI).
postoperatieve pijn na een heupvervanging THA

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Department of Orthopaedics
Reinier de Graaf Groep, afdeling orthopedie
Reinier de Graafweg 3-11
2625 AD Delft
Source(s) of monetary or material Support: einier de Graaf Groep
Department of Orthopaedics

Intervention

Outcome measures

Primary outcome

1. Pain score (VAS) at day 1 at multiple moments: 1, 4 and 8 hours after operation in rest, and while and direct after mobilization starting at 4-6 hours after operation. At day 2 until the day of discharge at two moments;

2. Cumulative consumption of opioid medication and pain medication;

3. Length of Hospital Stay by amount of nights and number of hours between operation and discharge.

Secondary outcome

N/A

Study description

Background summary

Rationale:

Local infiltration analgesia (LIA) is widely applied as part of a multimodal pain management strategy in total hip arthroplasty (THA). The optimal way of infiltration and dose of perioperative consummated pain medication are not known.

In Reinier de Graaf Groep (RdGG) the Anterior Supine Intermuscular technique (ASI) is being used for THA procedures. This technique will allow the patient to mobilize much earlier postoperatively compared to other techniques. However, it has been hypothesized that it will result in more pain directly postoperative. Therefore, this study will investigate the effect of LIA in combination with the ASI technique.

Objective:

Determining the outcome of reversed and antegrade LIA in THA with ASI by analysing postoperative pain with the 100 mm Visual Analogue Scale (VAS), length of hospital stay, the amount of postoperative consumption of opioid pain medication as well as the consumption of other pain medication. The amount of nausea and vomiting will also be determined.

Study design:

This study is a randomised, placebo controlled blind (for the patient) trial comparing the outcome in one group of interest, the total hip arthroplasty group, using three local infiltration analgesia (LIA) techniques.

Patients with coxarthrosis, who qualify for a THA by ASI, will get local infiltration analgesia during operation. They will be randomised into 3 groups. Group 1 will be given LIA by antegrade infiltration. Group 2 will be given LIA by reversed infiltration. Group 3 will be given placebo LIA by antegrade infiltration.

Study population:

Patients who are scheduled for a total hip arthroplasty at RdGG with ASA I or II and speak the Dutch language. Patients are 18y and older, willing to participate, able to give informed consent and not mentally retarded.

Main study parameters/endpoints:

1. Postoperative pain, measured using the VAS. Day 1 at multiple moments: 1, 4 and 8 hours after operation in rest. During and immediately after first mobilisation (4-6 h after operation); and day 2 until the day of discharge at two standard moments in the morning and in the afternoon;

2. Cumulative consumption of opioids;

3. Cumulative consumption of other pain medication;

4. Number of days in hospital;

5. Number of hours between operation and discharge;

6. Number of periods of postoperative vomiting;

7. Number and severity of postoperative nausea.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Patients will receive their planned THA. There will be three more clinical control moments to measure the VAS in comparison to normal THA-patients: one hour after operation, during and immediately after first mobilisation. Patients in the placebo group can have more pain when compared to the patients in the other two groups. All patients will receive rescue medication

when the standard pain medication is insufficient.

There will be no extra control moments after discharge when compared to normal THA-patients.

Study objective

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.

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.

Study design

Day of operation until discharge.

Intervention

This study is a randomised controlled trial, comparing the outcomes in patients with coxarthrosis after THA with the ASI technique. Patients will be randomised in an antegrade infiltration group, a reversed infiltration group and an antegrade placebo infiltration group. Peri- and postoperative they get standard pain medication.
There will be tree randomised groups:

1. Antegrade - Ropivacaine/epinephrine 120 ml;

2. Reversed - Ropivacaine/epinephrine 120 ml;

3. Antegrade - Placebo/Saline 120 ml.

Infiltration with 120 ml ropivacaine/epinephrine (ropivacaine 2 mg/ml, epinephrine 1 mg/ml). In total two syringes of 50 ml with 49,5 ml ropivacaine and 0,5 ml epinephrine and one syringe of 20 ml with 19,8 ml ropivacaine an s 0,2 ml epinephrine.

Antegrade infiltration:

1. After reaming the acetabulum, there will be a clockwise infiltration periacetabular with 50

ml ropivacaine/epinephrine or saline;

2. After placing the femoral component there will be an 10 ml ropivacaine/epinephrine or saline infiltration of the gluteus minimus muscle, 20 ml ropivacaine/epinephrine or saline in the gluteus medius muscle, and 20 ml ropivacaine/epinephrine or saline in the vastus lateralis muscle;

3. Just before closure of the wound, 20 ml of ropivacaine/epinephrine or saline is infiltrated in the subcutis.

Reversed infiltration:

1. Start with injection of 20 ml ropivacaine/epinephrine in the subcutis, followed by incision of the cutis and subcutis;

2. Infiltration of 50 ml ropivacaine/epinephrine of the gluteus medius muscle, gluteus minimus muscle, vastus lateralis muscle and the joint capsule, followed by incision of the joint capsule;

3. Just before reaming the acetabulum and placement of the cup and femoral component, the peri-acetabular region is infiltrated clockwise with 50 ml ropivacaine/epinephrine.

Contacts

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Eligibility criteria

Inclusion criteria

The hospital criteria and protocol for patients who are diagnosed for a total hip arthroplasty with osteoarthritis will be applied.

1. Patients aged 18 years and older;

2. Patients willing to participate;

3. ASA I and II.

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 and V;

6. Cardiovascular impairment in the past;

7. Abuse of alcohol or drugs;

8. Known allergy for any element of the medication that is given;

9. Medical contra indication for spinal anaesthesia;

10. BMI > 40;

11. Rheumatoid arthritis.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2012
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-02-2012
Application type:	First submission

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
NTR-new	NL3157
NTR-old	NTR3301
Other	METC / Reinier de Graaf Groep : 12-029 / 2012-002-M;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A