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

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Determining the outcome of reversed and antegrade LIA in THA with ASI by analysing postoperative pain with the 100 mm Visual Analogue Scale (NRS), length of hospital stay, the amount of postoperative consumption of opioid pain medication as well as...

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

Summary

ID

NL-OMON39407

Source
ToetsingOnline

Brief title
LIA in total hip arthroplasty

Condition

- Joint disorders

Synonym
pain after total hip arthroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Ministerie van OC&W,Maatschap Orthopedie RdGG

Intervention

Keyword: Anterior Supine Intermuscular Approach, Local infiltration anaeshesia, Total hip arthroplasty

Outcome measures

Primary outcome

- Pain score (NRS) 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. Also

during and immediately after mobilization.

- Preoperative pain will be scored during the preoperative

screening.

- POVN is asked at the moments the VAS is scored.

- Cumulative consumption of opioid medication and pain medication.

- Length of Hospital Stay by amount of nights and number of hours between

operation and discharge.

Secondary outcome

not applicable

Study description

Background summary

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.

Study objective

Determining the outcome of reversed and antegrade LIA in THA with ASI by analysing postoperative pain with the 100 mm Visual Analogue Scale (NRS), 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. Also, preoperative pain will be scored as well as the amount of medication used during surgery.

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.

Intervention

Local infiltration analgesia (LIA) during THA procedures.

Study burden and risks

Patients will receive their planned THA. There will be three more clinical control moments to measure the NRS 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.

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

The hospital criteria for patients diagnosted for a total hip arthroplasty with osteoarthritis will be applied
* Patients aged 18 years and older.
* Patients willing to participate.
* ASA I and II.

Exclusion criteria

* Patients unwilling to participate.
* Mentally retarded.
* Neurological conditions potentially influence pain perception.
* Psychiatric conditions potentially influence pain perception.
* ASA III, IV and V.
* Cardiovascular impairment inthe present and the past.
* Abuse of alcohol or drugs.
* Known allergy for any element of the medication that is given (ropivacain, epinephrin).
* Medical contra indication for spinal anaesthesia.

* BMI > 40.
* Rheumatoid arthritis.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2012
Enrollment:	75
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Epinephrin 1mg/ml PCH
Generic name:	Epinephrin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Ropivacain HCl Fresenius Kabi
Generic name:	Ropivacain HCl
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	12-03-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	01-06-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	02-11-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	09-08-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2012-000989-37-NL
CCMO	NL39970.098.12