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The effect of extra local anaesthesia during total hip arthroplasty

Submission date
11/07/2017

Recruitment status
No longer recruiting

Registration date
25/07/2017

Overall study status
Completed

Last Edited
17/01/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 anaesthia 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/ephinephrine. Those in the second group receive a reversed infiltration with ropivacaine/epinephrine. Those in the last group receive a placebo (a dummy) medication containg 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

Study website
N/A

Contact information

Type(s)
Public

Contact name
Miss Nina Mathijssen

Contact details
Reinier de Graaf Hospital
Reinier de Graafweg 5
Delft
Netherlands
2625AD

Additional identifiers

EudraCT/CTIS number
2012-000989-37

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)
METC ZuidWest Holland, 01/06/2012, ref: NL39970.098.12

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 topivacaine /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 measure
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.

Secondary outcome measures
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

Overall study start date
01/06/2011

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
75

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
Netherlands

United Kingdom

Study participating centre
Reinier de Graaf Hospital
Reinier de Graafweg 5
Delft
Netherlands
2625AD

Sponsor information

Organisation
Reinier de Graaf Groep, department of orthopaedics

Sponsor details
Reinier de Graafweg 5
Delft
Netherlands
2625AD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00wkhef66

Funder(s)

Funder type
Government

Funder Name
Reinier de Graaf Groep

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/01/2019

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?
Results article	results	24/08/2017		Yes	No