Local infiltration anesthesia in total knee arthroplasty

Published: 07-05-2012
Last updated: 01-05-2024

Optimizing the amount of ropivacain and gabapentin, used for local infiltration (LIA) during TKA procedures by measuring the outcomes of pain (by using the 100 mm Visual Analogue Scale (VAS)), adverse effects, length of hospital stay, cumulative...

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

Summary

ID

NL-OMON39330

Source
ToetsingOnline

Brief title
LIA in total knee arthroplasty

Condition

- Joint disorders

Synonym
Pain after total knee arthroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Maatschap orthopedie. Financiering vanuit het ziekenhuis (WAC) is aangevraagd voor blindering medicatie

Intervention

Keyword: Adverse effects, Local Infiltration Anesthesia, Ropivacain, Total Knee Arthroplasty

Outcome measures

Primary outcome

The main study parameters are pain scores and adverse effects after TKA with

LIA.

- 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 standardized

moments;

- Adverse effects (headache, nausea, vomiting, dizziness and sedation)

- Cumulative consumption of opioid medication and (rescue) pain medication.

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

operation and discharge.

- Wound leakage using a five point scale.

Secondary outcome

Not applicable

Study description

Background summary

Total Knee Arthroplasty (TKA) is associated with moderate to severe postoperative pain. This causes discomfort in mobilization and hospital discharge is extended. Severe postoperative pain is traditionally treated by (high doses of) opiates and NSAIDs but the side effects are numerous. Postoperative nausea and vomiting (PONV) are notorious and generate discomfort for the patient and extra costs by the need of anti-emetic drugs, longer

hospital stay and nursing care.
Past decade, local infiltration analgesia (LIA) is more and more applied as part of a multimodal pain management strategy in TKA and seems to have a lot of benefits. Less pain might results in early mobilisation, less consummation of opiates and a reduced hospital stay. The optimal dose and way of local infiltration and of perioperative consummated pain medication are not known. In the rapid recovery tract in TKA in our hospital an effective combination of 150ml ropivacain infiltration perioperative, 600 mg gabapentin preoperative and 300 mg gabapentin at day one postoperative are used. These high doses of ropivacain and gabapentin might cause multiple side effects (headache, nausea, vomiting, dizziness and sedation). Therefore, we would like to study the influence of reducing the amount of ropivacain perioperative and gabapentin pre- and postoperative on pain and side effects. This way, doses of both medications might be optimized.

Study objective

Optimizing the amount of ropivacain and gabapentin, used for local infiltration (LIA) during TKA procedures by measuring the outcomes of pain (by using the 100 mm Visual Analogue Scale (VAS)), adverse effects, length of hospital stay, cumulative pain medication consumption.

Study design

This study is a randomised controlled double blind trial, comparing the outcomes in patients with TKA and LIA.
Patients with unilateral gonarthrosis who qualify for a TKA will be randomly divided into four groups;
A. Current protocol: 150 ml ropivacain/epinephrine and 600/300/300 mg gabapentin pre-operation, 8h after operation and the morning after the operation.
B. 75 ml ropivacain/epinephrine and 600/300/300 mg gabapentin.
C. 150 ml ropivacain/epinephrine and 300/100/100 mg gabapentin.
D. 75 ml ropivacain/epinephrine and 300/100/100 mg gabapentin.

Intervention

Local infiltration analgesia (LIA) during TKA procedures.
Perioperative patients will be infiltrated and given painmedication in randomly divided four doses;
A. Current protocol: 150 ml ropivacain/epinephrine and 600/300/300 mg gabapentin pre-operation, 8h after operation and the morning after the operation.
B. 75 ml ropivacain/epinephrine and 600/300/300 mg gabapentin.
C. 150 ml ropivacain/epinephrine and 300/100/100 mg gabapentin.

D. 75 ml ropivacain/epinephrine and 300/100/100 mg gabapentin.

Study burden and risks

Patients will receive their planned TKA. There will be three more clinical control moments to measure the VAS and adverse effects in comparison to normal TKA-patients.: one hour after operation, during and immediatly after first mobilisation.Patients from all groups will receive their planned TKA. There will be no extra control moments when compared to TKA patient not participating in the study. Patients in the lower dosed groups can have more pain when compared to the patients in the higher dosed groups. All patients will receive rescue medication when standard pain medication is insufficient. There will be no extra control moments after discharge when compared to normal TKA-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 and protocol for patients who are diagnosed for a total knee arthroplasty in the outpatients* clinic of the Orthopaedic Department of RdGG Hospital Delft
* Patients at least 18 years of age
* Scheduled for elective total knee arthroplasty
* ASA I-III
* Willing to participate

Exclusion criteria

* age < 18
* ASA IV
* moderate or severe cardiac disease, bronchial asthma
* allergy against Ropivacain, Gabapentin, Epinephrin
* pregnancy
* severe psychiatric disease
* moderate to severe dementia, mentally retarded
* BMI > 40
* Abuse alcohol and drugs
* Chronic use of opioids
* Patients diagnosed Rheumatoid arthritis
* Revision TKA

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-09-2013
Enrollment:	128
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Epinephrin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Epinephrin 1mg/ml PCH
Generic name:	Epinephrin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Neurontin 100, 300, 600mg
Generic name:	Gabapentin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	07-05-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	28-08-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Not approved Date:	02-01-2013

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	04-09-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	20-10-2014
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	EUCTR2012-001432-62-NL
CCMO	NL40222.098.12