The effect of Local Infiltration Analgesia on postoperative pain in Total Knee Arthroplastia

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Reduction of the postoperative pain in Total Knee Arthroplatia through the use of a peri- and intracticular injection of Local Infiltration Analgesia.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON36098

Source
ToetsingOnline

Brief title
TOKNOWIT

Condition

- Bone and joint therapeutic procedures

Synonym
postoperative pain; pain

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: INFILTRATION, KNEE, POSTOPERATIVE PAIN, ROPIVACAIN

Outcome measures

Primary outcome

VAS-score 6 hours after operation

Secondary outcome

Pain management: need for opiates in the first 24 hours, incidence of severe pain (NRS >7) in the first 24 hours, VAS-score whilest leaving recovery, the evening after surgery and the first 4 days measured 3 times a day. Side effects: incidence and severity of nausea and vometing

Recovery: MILAS assistance scale, flexion of knee, hospital stay

Study description

Background summary

Total Knee Arthroplastia is a surgery that involves significant postoperative pain. The aim is an optimal postoperative pain management. Local Infiltration Analgesia (LIA) is a method that is becoming more and more standard care in preventing and reducing this postoperative pain.

Study objective

Reduction of the postoperative pain in Total Knee Arthroplatia through the use of a peri- and intracticular injection of Local Infiltration Analgesia.

Study design

Double-blinded, randomised, monocentre study

Intervention

Controlgroup: standard care: Peroperative placebo infiltration, postoperative

Patient Controlled Analgesia (PCA) with morfine during 20 hours.
Interventiongroup: peroperative peri- en intraarticular Local infiltratiion Analgesia (LIA) with ropivacaïne and adrenaline, postoperative: PCA with morfine during the first 20 hours.

Study burden and risks

The LIA-technique is standard care in several international hospitals. The safety of the method is already demonstrated. However, in these studies additional medication is used that is not registered in Holland. Or the technique is compared to a technique not used in the Meander MC.
Because ropivacaine and adrenaline are already long in the market, unknown side-effects are not expected.
Patients don't get additional interventions, no longer surgeries, no additional questionnaires and no extra discomfort other than that they would get when not participating in the study
There are no patients participating who are minor or incompetent.

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

Age > 18 years
Total knee arthroplastia of one knee
Short track program

Exclusion criteria

revision of former total knee arthroplastia, chronic use of opioids, use of steroids, bilateral surgery, contra-indication for spinal or epidural analgesia, ASA-score > 3, time of surgery > 2 hours, intolerance of study medication, epilepsia, sensibility disorder of the leg, former patellectomy, (acute of chronic) infection of the knee, psychiatric illness, neuromuscular effects, language barrier, immunologic disease, BMI > 40, alcohol abusus, pregnant women,

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2011
Enrollment:	82

Type:	Actual

Ethics review

Approved WMO Date:	12-07-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-09-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL35559.100.11