Adrenaline use in local infiltration analgesia during TKA;Randomized, double blind, controlled study

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The goal of the pilot study is to compare LIA with or without adrenaline infiltration by means of post operative pain (VAS) scores, PONV, early mobilisation and early discharge criteria.

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

Summary

ID

NL-OMON40518

Source
ToetsingOnline

Brief title
LIA with or without adrenaline in TKA

Condition

- Joint disorders

Synonym
knee wear, osteoarthritis of the knee joint

Research involving
Human

Sponsors and support

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

Intervention

Keyword: adrenaline, epinepherine, knee surgery, local anesthesia, pain management

Outcome measures

Primary outcome

VAS-painscore, post operative pain relief

- Direct after the operation

- Before and after the first mobilisation

- Pain measure 3 times a day on standard time 3 a day on fixed intervals until discharge

Secondary outcome

- Amount of post operative analgesia use direct post operative till day of discharge

- Time to fisrt mobilisation

- Length of hospital stay

- Adverse events/complications: Intra-operative, post-operative during pilot study

Study description

Background summary

Postoperative pain is one of the most common complaints after total knee arthroplasty. Excessive postoperative pain, nausea and/or vomiting (PONV) ensure to delay (early) mobilization, early recovery and are the most common reasons for unnecessary prolonged hospital stay. Early mobilisation of these patients frequently depends on recovery from anesthesia. Recently, a local infiltration analgesia (LIA) technique was developed by Kerr and Kohan(Sydney, Australia). With this LIA-technique, a long-acting local anesthetic (ropivacaine) is infiltrated intraoperatively. LIA is common described in

literature in total knee arthroplasty with favourable results. It decreases post operative pain and PONV and allows patients to mobilise within <6 hours post operative. These patients are able to be discharged 2 days earlier compared to patients not infiltrated with LIA. Local infiltration analgesia in knee joint replacement surgery is associated with reduced post operative pain relief, early mobilisation and hospital discharge. Combination of ropivacaine with adrenaline is common used in literature. With the following pilot study we want to determine whether adrenaline affects the postoperative pain relief after total knee arthroplasty.

Study objective

The goal of the pilot study is to compare LIA with or without adrenaline infiltration by means of post operative pain (VAS) scores, PONV, early mobilisation and early discharge criteria.

Study design

Clinical, Randomised, double blind, pilot study

Intervention

Local Infiltration analgesia with ropivacaine with or without adrenaline.

Study burden and risks

NA

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

• Painful and disabled knee joint resulting from osteoarthritis
• High need to obtain pain relief and improve function
• Able and willing to follow instructions
• Informed consent

Exclusion criteria

• Active infection in knee
• General infection
• Distant foci of infections which may spread to the implant site
• Failure of previous joint replacement
• Pregnancy

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-06-2014
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	epinephrine
Generic name:	epinephrine
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	09-05-2014
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	EUCTR2013-005401-31-NL
CCMO	NL45980.096.14