

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Joint disorders
<b>Study type</b>	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, epinephrine, 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 first 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**

### **Public**

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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

EudraCT

CCMO

### ID

EUCTR2013-005401-31-NL

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