CLINICAL PHARMACOKINETICS OF ROPIVACAINE USING LOCAL INFILTRATION ANESTHESIA (LIA) TECHNIQUE IN THE TOTAL KNEE ARTHROPLASTY: A PILOT STUDY

Published: 20-01-2012
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The primary objective is to assess the pharmacokinetics of ropivacaine after LIA in the local infiltration technique for patients with TKA.

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

Summary

ID

NL-OMON37901

Source
ToetsingOnline

Brief title
PHARO

Condition

- Bone and joint therapeutic procedures

Synonym
Total knee arthroplasty (total knee replacement)

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Reinier de Graaf Groep

Intervention

Keyword: LIA, Pharmacokinetic, Ropivacaine

Outcome measures

Primary outcome

The determination of pharmacokinetic parameters of ropivacaine after LIA in

patients with TKA.

Secondary outcome

Not applicable.

Study description

Background summary

The local infiltration anesthesia technique in patients with total knee arthroplasty is a standard used treatment in the Reinier de Graaf Groep hospital. Much is known, including the efficacy, but the pharmacokinetics are not yet been fully clarified. Therefore, in this study the pharmacokinetics are determined, with the aim of future research on dose finding.

Study objective

The primary objective is to assess the pharmacokinetics of ropivacaine after LIA in the local infiltration technique for patients with TKA.

Study design

Prospective cohort study

Study burden and risks

This study brings neither extra risks nor benefits directly for the patients.
The patients receive the same care, as usual in TKA care using this kind of

anesthesia techniques. The additional load is catherisation and 9 extra blood samples of 2-3 mL for the determination of PK data collected with an indwelling venous catheter (Venflon) in addition to routine blood sampling in the TKA procedure.
Simultaneously with the blood sampling, patients, nurses and ward doctors will be asked to report and document the intensity and frequency of PONV on a questionnaire (standard policy). Additional on the questionnaire, the pain intensity will be asked, with the use of an eleven point Visual Analogue Scale (0-10, 0 = no pain; 10 = unbearable pain). The time of each survey will be logged precisely.

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

- Totaal knee arthroplasty surgery
- Age older than 18 years
- Willing to participate in the study after consultation and written informed consent after Pre-Operative Screening (POS)

Exclusion criteria

- Known allergy to amide type local anaesthetics or for any other drugs used routinely during this type of surgery
- Mentally retarded
- Taking opiates or antiemetics (other than used in the protocol and used prior to the POS)
- Taking CYP1A2 inhibitors
- Taking CYP3A4 inhibitors
- Liver failure (ALAT, ASAT, gamma-GT and bilirubin > 3 times upper reference value)- Renal failure (GFR <30 ml/min)
- Known alcohol (drink more than 5 alcohol units in any one day), drug or medication abuse. (noted during the POS)
- Renal failure (GFR <30 ml/min, determined with measuring the serum creatin and using the Cockroft-Gault formula)
- Severe obesity (BMI *40)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-02-2012
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	20-01-2012
Application type:	First submission
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
CCMO	NL38840.098.11