

**Clinical trial results:  
Pharmacokinetic Profile of Ropivacaine after Periarticular Local  
Infiltration Analgesia for Primary Total Knee Arthroplasty****Summary**

EudraCT number	2014-003010-93
Trial protocol	NL
Global end of trial date	30 May 2015

**Results information**

Result version number	v1 (current)
This version publication date	11 January 2022
First version publication date	11 January 2022
Summary attachment (see zip file)	Pharmacokinetics of 400 mg ropivacaine after periarticular local infiltration analgesia for total knee arthroplasty (Artikel LIAkin Acta.pdf)

**Trial information****Trial identification**

Sponsor protocol code	620
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**Additional study identifiers**

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

**Sponsors**

Sponsor organisation name	Sint Maartenskliniek
Sponsor organisation address	Hengstdal 3, Ubbergen, Netherlands,
Public contact	afdeling Research, Sint Maartenskliniek, secretariaat.rde@maartenskliniek.nl
Scientific contact	afdeling Research, Sint Maartenskliniek, secretariaat.rde@maartenskliniek.nl

Notes:

**Paediatric regulatory details**

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 July 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 May 2015
Global end of trial reached?	Yes
Global end of trial date	30 May 2015
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

Although considered safe, no pharmacokinetic data of high dose, high volume local infiltration analgesia (LIA) with ropivacaine without the use of a surgical drain or intra-articular catheter have been described. The purpose of this study is to describe the maximum total and unbound ropivacaine concentrations (C<sub>max</sub>, C<sub>u max</sub>) and corresponding maximum times (T<sub>max</sub>, T<sub>u max</sub>) of a single-shot ropivacaine (200 ml 0.2%) and 0.75 mg epinephrine (1000 lg/ml) when used for LIA in patients for total knee arthroplasty.

Protection of trial subjects:

all study patients were treated according to standard hospital protocol and blood was drawn from an indwelling IV catheter.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	1
From 65 to 84 years	19



## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

scheduled for primary total knee replacement

50-80 years

ASA score I or II

BMI < 40 kg/m<sup>2</sup>

Hb > 7.5 mmol/L

### Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

### Arms

<b>Arm title</b>	study patients
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Arm description:

all study patients are enrolled in the one same study without any distinction between them and no groups made

Arm type	Experimental
Investigational medicinal product name	ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Infiltration

Dosage and administration details:

400 mg ropivacaine in 200 mL (0.2%) is infiltrated in and around the knee

<b>Number of subjects in period 1</b>	study patients
Started	20
Completed	20

## Baseline characteristics

### Reporting groups

Reporting group title	overall trial
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Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	20	20	
Age categorical			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: years			
arithmetic mean	58.5		
standard deviation	± 6.7	-	
Gender categorical			
Units: Subjects			
Female	8	8	
Male	12	12	

## End points

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### End points reporting groups

Reporting group title	study patients
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Reporting group description:

all study patients are enrolled in the one same study without any distinction between them and no groups made

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### Primary: Cmax

End point title	Cmax <sup>[1]</sup>
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End point description:

End point type	Primary
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End point timeframe:

baseline, 20, 40, 60, 90, 120, 240, 360, 480, 600, 720 and 1440 minutes after closure of the wound.

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Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: data are descriptive, no comparison is made therefore no statistical comparison is available

<b>End point values</b>	study patients			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: microgram(s)/millilitre				
median (inter-quartile range (Q1-Q3))	1.00 (0.66 to 1.34)			

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### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

during study enrollment (from start of surgery until 1440 minutes after wound closure)

Assessment type                      Systematic

### Dictionary used

Dictionary name                      toetsingonline

Dictionary version                      1

### Reporting groups

Reporting group title                      study group

Reporting group description: -

<b>Serious adverse events</b>	study group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

<b>Non-serious adverse events</b>	study group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: during this very short study period and very small sample size no non-serious adverse events are recorded

## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported

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### **Online references**

<http://www.ncbi.nlm.nih.gov/pubmed/28066882>