Clinical trial results:
Pharmacokinetic Profile of Ropivacaïne 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

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 (Cmax, Cu max) and corresponding maximum times (Tmax, Tu max) 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

85 years and over	0

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/m2
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

Arm title	study patients

Arm description:

all study patients are enrolled in the one same study without any distiction 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

Number of subjects in period 1	study patients
Started	20
Completed	20

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

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

End points reporting groups

Reporting group title	study patients

Reporting group description:

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

Primary: Cmax

End point title	Cmax[1]

End point description:

End point type	Primary

End point timeframe:

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

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

End point values	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)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

during study enrollment (from start of surgery untill 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: -

Serious adverse events	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 %

Non-serious adverse events	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

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

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