Clinical trial results:
Comparison of 2-chloroprocaïne, bupivacaïne and lidocaïne for spinal anesthesia in knee artroscopy in an outpatient setting: a double blind randomised trial

Summary

EudraCT number	2011-003675-11
Trial protocol	BE
Global end of trial date	30 May 2014

Results information

Result version number	v1 (current)
This version publication date	08 February 2020
First version publication date	08 February 2020

Trial information

Trial identification

Sponsor protocol code	AT06/2011

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	UZ Leuven
Sponsor organisation address	Herestraat 9, Leuven, Belgium,
Public contact	Research Anesthesiology, University Hospitals Leuven, 32 16344270, christel.huygens@uzleuven.be
Scientific contact	Research Anesthesiology, University Hospitals Leuven, 32 16344270, christel.huygens@uzleuven.be

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	08 October 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 May 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

We want to investigate the optimal anesthesia for knee arthroscopy in a day-case setting

Protection of trial subjects:

All patients received standard preemptive pain medication with ketorolac and Paracetamol.
In case of insufficient spinal anesthesia, a general anesthesia was performed

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 September 2011
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	Belgium: 99
Worldwide total number of subjects	99
EEA total number of subjects	99

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)	90
From 65 to 84 years	9
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

In this prospective, double-blind, randomised controlled clinical trial, 99 patients scheduled for diagnostic knee arthroscopy in an ambulatory setting were included.

Pre-assignment

Screening details:

We included patients aged 18 years and older who were scheduled for elective knee arthroscopy under spinal anesthesia and having an ASA (American Society of Anesthesiologists') physical status I-III. Exclusion criteria were patients using anti-depressant drugs and/ or anti-psychotic medication, allergies to local anesthetics and known prostate hype

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Arms

Are arms mutually exclusive?	Yes
Arm title	chloroprocaine group

Arm description: -

Arm type	Experimental
Investigational medicinal product name	2-Chloroprocaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intratracheal use

Dosage and administration details:

40 mg of plain preservative free 2-chloroprocaine 1% was injected intrathecally

Arm title	Lidocaine

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Lidocaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intrathecal use

Dosage and administration details:

40 mg of plain lidocaine 1% was injected intrathecally

Arm title	Bupivacaine

Arm description: -

Arm type	Experimental
Investigational medicinal product name	bupivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intrathecal use

Dosage and administration details:
7.5 mg of plain bupivacaine 0.5% was injected intrathecally

Number of subjects in period 1	chloroprocaine group	Lidocaine	Bupivacaine
Started	32	32	35
Completed	32	32	35

Baseline characteristics

Reporting groups	
Reporting group title	chloroprocaine group
Reporting group description: -	
Reporting group title	Lidocaine
Reporting group description: -	
Reporting group title	Bupivacaine
Reporting group description: -	

Reporting group values	chloroprocaine group	Lidocaine	Bupivacaine
Number of subjects	32	32	35
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous Units: years			
median	47.5	48	49
full range (min-max)	21 to 76	19 to 72	20 to 66
Gender categorical Units: Subjects			
Female	11	10	19
Male	21	22	16

Reporting group values	Total		
Number of subjects	99		
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 median full range (min-max)	--		
Gender categorical Units: Subjects			
Female	40		
Male	59		

End points

End points reporting groups

Reporting group title	chloroprocaine group
Reporting group description: -	
Reporting group title	Lidocaine
Reporting group description: -	
Reporting group title	Bupivacaine
Reporting group description: -	

Primary: Time until complete recovery of the sensory block

End point title	Time until complete recovery of the sensory block
End point description:	
End point type	Primary
End point timeframe:	
Time until recovery of sensation to S5	

End point values	chloroprocaine group	Lidocaine	Bupivacaine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	30	28	34	
Units: hours				
median (inter-quartile range (Q1-Q3))	2.6 (2.2 to 2.9)	3.1 (2.7 to 3.6)	6.1 (5.5 to 8)	

Statistical analyses

Statistical analysis title	Recovery of motor block
Comparison groups	chloroprocaine group v Lidocaine v Bupivacaine
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01667
Method	Wilcoxon (Mann-Whitney)

Secondary: Complete recovery of motor block

End point title	Complete recovery of motor block
End point description:	
End point type	Secondary

End point timeframe:
Time until a Bromage score of 0 was reached

End point values	chloroprocaine group	Lidocaine	Bupivacaine	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	30	28	34	
Units: hours				
median (inter-quartile range (Q1-Q3))	1.48 (1.32 to 1.8)	1.83 (1.56 to 2.17)	3.25 (2 to 4.17)	

Statistical analyses

Statistical analysis title	Recovery of sensory block
Comparison groups	chloroprocaine group v Lidocaine v Bupivacaine
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01667
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	Recovery of motor block
Comparison groups	chloroprocaine group v Lidocaine v Bupivacaine
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01667
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
All patients were observed for adverse events until 24 hours postoperatively.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.1

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

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: Patients were monitored for transient neurological symptoms, but no patients complained postoperatively.

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/27281722