



## Clinical trial results:

### Chloroprocaine vs prilocaine for spinal anaesthesia in day-case surgery: a double-blind randomized trial

#### Summary

EudraCT number	2015-001944-13
Trial protocol	NL
Global end of trial date	22 June 2018

#### Results information

Result version number	v1 (current)
This version publication date	28 January 2022
First version publication date	28 January 2022
Summary attachment (see zip file)	Abstract & results (DEF rapm-2019-100673.full.pdf)

#### Trial information

##### Trial identification

Sponsor protocol code	ZAA15CPP
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##### Additional study identifiers

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

Notes:

#### Sponsors

Sponsor organisation name	Zaans Medisch Centrum
Sponsor organisation address	Koningin Julianaplein 58, Zaandam, Netherlands, 1502 DV
Public contact	Clinical trials information, Zaans Medisch Centrum, wesselink.e@zaansmc.nl
Scientific contact	Clinical trials information, Zaans Medisch Centrum, wesselink.e@zaansmc.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:

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**Results analysis stage**

Analysis stage	Final
Date of interim/final analysis	05 May 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 May 2018
Global end of trial reached?	Yes
Global end of trial date	22 June 2018
Was the trial ended prematurely?	No

Notes:

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**General information about the trial**

Main objective of the trial:

To investigate effectiveness of spinal chloroprocaine, and prilocaine in day case surgery. The null hypothesis is that there is no significant intergroup difference in time to complete recovery from motor blockade.

Protection of trial subjects:

METC approval

Background therapy: -

Evidence for comparator: -

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

Notes:

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**Population of trial subjects****Subjects enrolled per country**

Country: Number of subjects enrolled	Netherlands: 150
Worldwide total number of subjects	150
EEA total number of subjects	150

Notes:

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**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)	132
From 65 to 84 years	18
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

150 patients were randomly allocated to receive intrathecally either 40 mg of 2-chloroprocaine or 40 mg of prilocaine.

### Pre-assignment

Screening details:

Patients scheduled for knee arthroscopy with spinal anesthesia were eligible for participation in the study if they were 18 years or older and had an American Society of Anesthesiologists' physical status I-II.

### 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, Carer, Assessor, Investigator

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Prilocaine

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Prilocaine 40 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solvent for parenteral use
Routes of administration	Intrathecal use

Dosage and administration details:

40 mc intrathecal

<b>Arm title</b>	chloroprocaine
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Arm description: -

Arm type	Active comparator
Investigational medicinal product name	chloroprocaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intratracheal use

Dosage and administration details:

chloroprocaine 40 mg intrathecal

<b>Number of subjects in period 1</b>	Prilocaine	chloroprocaine
Started	75	75
Completed	75	75

## Baseline characteristics

### Reporting groups

Reporting group title	Prilocaine
Reporting group description: -	
Reporting group title	chloroprocaine
Reporting group description: -	

Reporting group values	Prilocaine	chloroprocaine	Total
Number of subjects	75	75	150
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	49.8	54.0	
standard deviation	± 11.2	± 12.5	-
Gender categorical Units: Subjects			
Female	31	34	65
Male	44	41	85

### Subject analysis sets

Subject analysis set title	Prilocaine
Subject analysis set type	Intention-to-treat
Subject analysis set description: Prilocaine	
Subject analysis set title	Chloroprocaine
Subject analysis set type	Intention-to-treat
Subject analysis set description: Chloroprocaine	

Reporting group values	Prilocaine	Chloroprocaine	
Number of subjects	75	75	
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 arithmetic mean standard deviation	49.9 ± 11.2	54.0 ± 12.5	
Gender categorical Units: Subjects			
Female	31	34	
Male	44	41	

## End points

### End points reporting groups

Reporting group title	Prilocaine
Reporting group description: -	
Reporting group title	chloroprocaine
Reporting group description: -	
Subject analysis set title	Prilocaine
Subject analysis set type	Intention-to-treat
Subject analysis set description: Prilocaine	
Subject analysis set title	Chloroprocaine
Subject analysis set type	Intention-to-treat
Subject analysis set description: Chloroprocaine	

### Primary: Time to full motor block recovery

End point title	Time to full motor block recovery
End point description:	
End point type	Primary
End point timeframe: 15 minutes	

End point values	Prilocaine	chloroprocaine	Prilocaine	Chloroprocaine
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	64	73	75	60
Units: minutes				
number (confidence interval 5%)	75 (60 to 90)	60 (60 to 82.5)	75 (60 to 90)	60 (60 to 82.5)

<b>Attachments (see zip file)</b>	Fig 1. Consort 2010 Flow Diagram.jpg
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### Statistical analyses

<b>Statistical analysis title</b>	Statistics
Statistical analysis description: For all variables, double data entry was used for verification and reconciliation in case of transcription errors and discrepancies caused by illegible data. Categorical variables were summarized per group by means of frequencies and percentages and compared between groups using the chi-square test or using Fisher's exact test in case of an expected cell count below 5. Continuous variables that were normally distributed were summarized by their mean and standard deviation.	
Comparison groups	Prilocaine v chloroprocaine

Number of subjects included in analysis	137
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	Chi-squared
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	2-sided
Variability estimate	Standard deviation



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

7 days postoperative

Assessment type	Systematic
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### Dictionary used

Dictionary name	AE_ARTS_E1_C1_1
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Dictionary version	1
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### Reporting groups

Reporting group title	Prilocaine
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Reporting group description: -

Reporting group title	Chloroprocaine
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Reporting group description: -

Serious adverse events	Prilocaine	Chloroprocaine	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 75 (1.33%)	1 / 75 (1.33%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
General disorders and administration site conditions			
Prolonged hospital stay	Additional description: Prolonged hospital stay due to nausea&vomiting or pain		
subjects affected / exposed	1 / 75 (1.33%)	1 / 75 (1.33%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 1.3 %

Non-serious adverse events	Prilocaine	Chloroprocaine	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 75 (5.33%)	2 / 75 (2.67%)	
Surgical and medical procedures			
Conversion to General Anesthesia	Additional description: spinal anesthesia failure		
subjects affected / exposed	4 / 75 (5.33%)	2 / 75 (2.67%)	
occurrences (all)	6	6	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 March 2017	age 18-64 was changed to >18 years, this was more representative for the population BMI<30 was changed to 'no BMO' limitations, this was more representative for the population  Both inclusion criteria were approved by the METC

Notes:

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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/31439640>