Clinical trial results:
Comparative study with prilocaine 1% and prilocaine 1.5% for ultrasound guided axillary brachial plexus blockade

Summary

EudraCT number	2015-002744-14
Trial protocol	BE
Global end of trial date	13 March 2017

Results information

Result version number	v1 (current)
This version publication date	28 August 2020
First version publication date	28 August 2020
Summary attachment (see zip file)	Results Summary (RAPM submission.pdf)

Trial information

Trial identification

Sponsor protocol code	PRILPLEXUS1%-1.5%

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	UZ Brussels
Sponsor organisation address	Laarbeeklaan 101, Jette, Belgium, 1090
Public contact	Data Nurse, Universitair Ziekenhuis Brussel, +32 24763134, veerle.vanmossevelde@uzbrussel.be
Scientific contact	Data Nurse, Universitair Ziekenhuis Brussel, +32 24763134, veerle.vanmossevelde@uzbrussel.be
Sponsor organisation name	UZ Brussels
Sponsor organisation address	Laarbeeklaan 101, Jette, Belgium, 1090
Public contact	Evelien Vandeurzen, University Hospital Brussels, 0032 24749237, evelien.vandeurzen@uzbrussel.be
Scientific contact	Evelien Vandeurzen, UZ Brussel, 0032 24749237, evelien.vandeurzen@uzbrussel.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	13 March 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 March 2017
Global end of trial reached?	Yes
Global end of trial date	13 March 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

In this study we will investigate the difference between prilocaine 1% and prilocaine 1.5% in relation to the time of onset of sensory and motor blockade and the quality and the duration of the block. In addition we will investigate if there is an effect of prilocaine in the used doses on the methemoglobinemia.

Protection of trial subjects:

If a block failed, patients received a rescue block or if necessary general anesthesia. Supplemental anesthesia was sometimes also given if complaints of discomfort.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2015
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 60
Worldwide total number of subjects	60
EEA total number of subjects	60

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)	39
From 65 to 84 years	21
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

It was conducted at the Universitair Ziekenhuis Brussel (Brussels University Hospital). A total of 60 patients, ASA I-III, scheduled for elective minor hand or for forearm surgery were included. Patients were assessed for eligibility durig the preoperative anesthesia consultation.

Pre-assignment

Screening details:

Exclusion criteria were: age < 18 years old, contra-indications for loco-regional anesthesia, and peripheral neurological disorders. Diabetic patients were included unless peripheral polyneuropathy was diagnosed or suspected.

Period 1

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

Blinding implementation details:

Patient did not know which block they were receiving. Only physician knew.

Arms

Are arms mutually exclusive?	Yes
Arm title	Group A

Arm description:

Patients receive prilocaine 1%

Arm type	Experimental
Investigational medicinal product name	Prilocaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Infiltration

Dosage and administration details:

20 ml of prilocaine 1% for group A. Prilocaine 2% was diluted with normal saline to obtain 20 ml of the desired concentration.

Arm title	Group B

Arm description:

Prilocaine 1.5%

Arm type	Experimental
Investigational medicinal product name	Prilocaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Infiltration

Dosage and administration details:

20 ml of prilocaine 1.5% for group B. Prilocaine 2% was diluted with normal saline to obtain 20 ml of the desired concentration.

Number of subjects in period 1	Group A	Group B
Started	30	30
Completed	26	29
Not completed	4	1
Lack of efficacy	4	1

Baseline characteristics

End points

End points reporting groups

Reporting group title	Group A
Reporting group description: Patients receive prilocaine 1%	
Reporting group title	Group B
Reporting group description: Prilocaine 1.5%	

Primary: Overall duration of sensory and motor block

End point title	Overall duration of sensory and motor block
End point description:	
End point type	Primary
End point timeframe: 5 Hours after block placement.	

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	29		
Units: minute				
number (not applicable)	26	29		

Attachments (see zip file)	Excel file/Copy of Studiepatienten 2 groepen.xlsx

Statistical analyses

Statistical analysis title	M-ANOVA test
Comparison groups	Group A v Group B
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	ANOVA
Parameter estimate	Mean difference (final values)
Variability estimate	Standard deviation

Primary: Methemoglobin level

End point title	Methemoglobin level

End point description:

End point type	Primary

End point timeframe:

2 hours after block placement.

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	29		
Units: percent volume/volume				
number (not applicable)	26	29		

Attachments (see zip file)	Table 2/RAPM submission.pdf

Statistical analyses

Statistical analysis title	M-ANOVA test
Comparison groups	Group A v Group B
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	ANOVA
Parameter estimate	Mean difference (final values)

Primary: Patient satisfaction

End point title	Patient satisfaction

End point description:

End point type	Primary

End point timeframe:

Post-operative asked questionnaire

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	29		
Units: scale of 1-10	26	29		

Attachments (see zip file)	See Column N/Copy of Studiepatienten 2 groepen.xlsx

Statistical analyses

Statistical analysis title	M-ANOVA test
Comparison groups	Group A v Group B
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	ANOVA

Secondary: Local anesthetic systemic toxicity

End point title	Local anesthetic systemic toxicity

End point description:

End point type	Secondary

End point timeframe:

6 months after surgery

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	29		
Units: number of patients with complaints	26	29		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: Start of surgery till 6 months post-op.	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	4.0

Reporting groups	
Reporting group title	Total group

Reporting group description: -

Serious adverse events	Total group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 60 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Total group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 60 (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: There were no adverse events reported.

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