Clinical trial results:
Effect of local anesthetic dose versus volume on block duration of single shot ultrasound-guided axillary brachial plexus block with mepivacaine

Summary

EudraCT number	2012-001704-38
Trial protocol	NL
Global end of trial date	18 June 2014

Results information

Result version number	v1 (current)
This version publication date	15 January 2022
First version publication date	15 January 2022

Trial information

Trial identification

Sponsor protocol code	NL40000.072.012

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	Clinical Trials Information, Sint Maartenskliniek, m.fenten@maartenskliniek.nl
Scientific contact	Clinical Trials Information, Sint Maartenskliniek, m.fenten@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	03 August 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 June 2014
Global end of trial reached?	Yes
Global end of trial date	18 June 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of the present study is to determine the effect of mepivacaine dose and volume on the duration of sensory axillary brachial plexus block (overall and individual nerves).

Protection of trial subjects:

pain treatment according to standard hospital protocol

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 April 2012
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: 49
Worldwide total number of subjects	49
EEA total number of subjects	49

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)	42
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were assessed for eligibility during the preoperative screening visit. Patients were informed about the study verbally and in writing and written informed consent was obtained from all patients.

Pre-assignment

Screening details:

Eligible patients were adults aged 18 or over with ASA physical health classification I–III, scheduled for single-injection ABPB for hand, wrist or forearm surgery. Exclusion criteria were infection at the injection site, coagulopathy, known hypersensitivity to amide-type local anesthetics, and kknown history of peripheral neuropathy.

Period 1

Period 1 title	overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Data analyst, Assessor

Blinding implementation details:

The anesthetic nurse that prepared the study medication was allowed to disclose allocation to the anesthesiologist that performed the block procedure. Both patients and researcher were blinded for the volume and concentration of anesthetic solution used.

Arms

Are arms mutually exclusive?	Yes
Arm title	Group A: 20 mL mepivacaine 1.5 %

Arm description: -

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

Dosage and administration details:

The patient was placed in the supine position with the head facing away from the arm to be blocked, the arm abducted and the elbow flexed in 90°. A 100-mm 22-gauge insulated short bevel needle (Stimuplex®; B. Braun, Melsungen, Germany) was inserted laterally in the axilla under ultrasound guidance. The musculocutaneous, median, ulnar and radial nerve were identified using ultrasound and the tip of the needle was brought in proximity of each individual nerve subsequently. The needle was connected to a nerve stimulator (Stimuplex® HNS 11; B. Braun) set to deliver 100 nC (0.1 ms, 1 mA) in order to facilitate identification of the individual nerves. The nerves were identified and blocked separately with one fourth of the study medication per nerve. Per patient one skin puncture was made, the needle was retracted subcutaneously and redirected under ultrasound guidance to approach the nerves individually.

Arm title	Group B: 30 mL mepivacaine 1.0 %

Arm description: -

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

Dosage and administration details:

The patient was placed in the supine position with the head facing away from the arm to be blocked, the

arm abducted and the elbow flexed in 90°. A 100-mm 22-gauge insulated short bevel needle (Stimuplex®; B. Braun, Melsungen, Germany) was inserted laterally in the axilla under ultrasound guidance. The musculocutaneous, median, ulnar and radial nerve were identified using ultrasound and the tip of the needle was brought in proximity of each individual nerve subsequently. The needle was connected to a nerve stimulator (Stimuplex® HNS 11; B. Braun) set to deliver 100 nC (0.1 ms, 1 mA) in order to facilitate identification of the individual nerves. The nerves were identified and blocked separately with one fourth of the study medication per nerve. Per patient one skin puncture was made, the needle was retracted subcutaneously and redirected under ultrasound guidance to approach the nerves individually.

Arm title	Group C: 30 mL mepivacaine 1.5 %
Arm description: -	
Arm type	Active comparator
Investigational medicinal product name	mepivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

The patient was placed in the supine position with the head facing away from the arm to be blocked, the arm abducted and the elbow flexed in 90°. A 100-mm 22-gauge insulated short bevel needle (Stimuplex®; B. Braun, Melsungen, Germany) was inserted laterally in the axilla under ultrasound guidance. The musculocutaneous, median, ulnar and radial nerve were identified using ultrasound and the tip of the needle was brought in proximity of each individual nerve subsequently. The needle was connected to a nerve stimulator (Stimuplex® HNS 11; B. Braun) set to deliver 100 nC (0.1 ms, 1 mA) in order to facilitate identification of the individual nerves. The nerves were identified and blocked separately with one fourth of the study medication per nerve. Per patient one skin puncture was made, the needle was retracted subcutaneously and redirected under ultrasound guidance to approach the nerves individually.

Number of subjects in period 1	Group A: 20 mL mepivacaine 1.5 %	Group B: 30 mL mepivacaine 1.0 %	Group C: 30 mL mepivacaine 1.5 %
Started	16	18	15
Completed	15	15	15
Not completed	1	3	0
Consent withdrawn by subject	1	-	-
block failure	-	3	-

Baseline characteristics

Reporting groups	
Reporting group title	overall study

Reporting group description: -

Reporting group values	overall study	Total	
Number of subjects	49	49	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	42	42	
From 65-84 years	7	7	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	34	34	
Male	15	15	

End points

End points reporting groups	
Reporting group title	Group A: 20 mL mepivacaine 1.5 %
Reporting group description: -	
Reporting group title	Group B: 30 mL mepivacaine 1.0 %
Reporting group description: -	
Reporting group title	Group C: 30 mL mepivacaine 1.5 %
Reporting group description: -	

Primary: duration of axillary plexus nerve block	
End point title	duration of axillary plexus nerve block
End point description:	
End point type	Primary
End point timeframe: total duration	

End point values	Group A: 20 mL mepivacaine 1.5 %	Group B: 30 mL mepivacaine 1.0 %	Group C: 30 mL mepivacaine 1.5 %	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	15	15	15	
Units: minutes				
arithmetic mean (confidence interval 95%)				
overall sensory	256 (230 to 282)	226 (209 to 243)	270 (248 to 291)	
overall motor	254 (226 to 282)	220 (200 to 240)	264 (244 to 284)	

Statistical analyses

Statistical analysis title	one-way ANOVA was used and Tukey post-hoc analyses
Comparison groups	Group A: 20 mL mepivacaine 1.5 % v Group B: 30 mL mepivacaine 1.0 % v Group C: 30 mL mepivacaine 1.5 %
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.05
Method	ANOVA

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

for each subject the study duration is defined from the start of the block placement until the return of full motor and sensory skills of all nerves.

Assessment type	Non-systematic

Dictionary used

Dictionary name	none
Dictionary version	0

Frequency threshold for reporting non-serious adverse events: 1 %

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: this relatively short duration of the study and the small number of study participants is probably the reason that no SAE's took place

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Three patients were excluded because of block failure, all in Group B. Our study was not set up nor powered to assess success rate of the different concentrations. From a clinical perspective, 1 % mepivacaine may not be a suitable choice for ABPB

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/26423050