Clinical trial results:
DEXMEDETOMIDINE FOR PERIPHERAL NERVE BLOCKADE: A DOSE-FINDING STUDY IN VOLUNTEERS

Summary

EudraCT number	2013-003790-10
Trial protocol	AT
Global end of trial date	24 December 2013

Results information

Result version number	v1 (current)
This version publication date	25 February 2016
First version publication date	25 February 2016
Summary attachment (see zip file)	Publication_EudraCT 2013-003790-10 (Publication_ EudraCT 2013-003790-10.pdf)

Trial information

Trial identification

Sponsor protocol code	1.0

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Währinger Gürtel 18-20, Vienna, Austria, 1090
Public contact	Maya Keplinger, Medical University of Vienna, 0043 1404004100, maya.keplinger@meduniwien.ac.at
Scientific contact	Maya Keplinger, Medical University of Vienna, 0043 1404004100, maya.keplinger@meduniwien.ac.at

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	18 February 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 December 2013
Global end of trial reached?	Yes
Global end of trial date	24 December 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Duration of sensory block of the ulnar nerve

Protection of trial subjects:

Subject were during the trial continuously under the supervision of a physician or an experienced nurse.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 November 2013
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	Austria: 24
Worldwide total number of subjects	24
EEA total number of subjects	24

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)	24
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruitet by use of the data base of the Clinical Pharmacology, Medical University Vienna.

Pre-assignment

Screening details:

Check of the In- and Exclusion criteria, Physical examination, Vital signs, Laboratory assessment

Pre-assignment period milestones

Number of subjects started	24
Number of subjects completed	24

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, Data analyst

Blinding implementation details:

The study drugs will be prepared by a study nurse outside the area where the blocks are performed. Both the anaesthetist and the volunteers are not informed about the adjuvants for LA for ulnar nerve blockade. All sensory tests will be performed by a study physician not otherwise involved in the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Group R

Arm description:

Group R: 3 ml ropivacaine without adjuvants

Arm type	active control
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	N01BB09
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Administration of 22.5mg Ropivacaine perineural as single dose

Arm title	Group RD50

Arm description:

Group RD50: 22.5 mg ropivacaine mixed with 50 µg dexmedetomidine

Arm type	Active comparator
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	N01BB09
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Administration of 22.5 mg ropivacaine mixed with 50 µg dexmedetomidine perineural as a single dose

Investigational medicinal product name	Dexmedetomidine
Investigational medicinal product code	29332990
Other name	Dexdor
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Perineural use

Dosage and administration details:

Administration of 22.5 mg ropivacaine mixed with 50 µg dexmedetomidine perineural as a single dose

Arm title	Group RD100

Arm description:

Group RD100: 22.5 mg ropivacaine mixed with 100 µg dexmedetomidine

Arm type	Active comparator
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	N01BB09
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Administration of 22.5 mg ropivacaine mixed with 100 µg dexmedetomidine perineural as a single dose

Investigational medicinal product name	Dexmedetomidine
Investigational medicinal product code	29332990
Other name	Dexdor
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Perineural use

Dosage and administration details:

Administration of 22.5 mg ropivacaine mixed with 100 µg dexmedetomidine perineural as a single dose

Arm title	Group RD150

Arm description:

Group RD150: 22.5 mg ropivacaine mixed with 150 µg dexmedetomidine

Arm type	Active comparator
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	N01BB09
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Administration of 22.5 mg ropivacaine mixed with 150 µg dexmedetomidine perineural as a single dose

Investigational medicinal product name	Dexmedetomidine
Investigational medicinal product code	29332990
Other name	Dexdor
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Perineural use

Dosage and administration details:

Administration of 22.5 mg ropivacaine mixed with 150 µg dexmedetomidine perineural as a single dose

Number of subjects in period 1	Group R	Group RD50	Group RD100
Started	6	6	6
Completed	6	6	6

Number of subjects in period 1	Group RD150
Started	6
Completed	6

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	24	24	
Age categorical			
18 to 45 years of age			
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)	24	24	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
18 to 45			
Units: years			
arithmetic mean	0		
standard deviation	± 24	-	
Gender categorical			
Units: Subjects			
Female	0	0	
Male	24	24	

End points

End points reporting groups

Reporting group title	Group R
Reporting group description:	
Group R: 3 ml ropivacaine without adjuvants	

Reporting group title	Group RD50
Reporting group description:	
Group RD50: 22.5 mg ropivacaine mixed with 50 µg dexmedetomidine	
Reporting group title	Group RD100
Reporting group description:	
Group RD100: 22.5 mg ropivacaine mixed with 100 µg dexmedetomidine	
Reporting group title	Group RD150
Reporting group description:	
Group RD150: 22.5 mg ropivacaine mixed with 150 µg dexmedetomidine	
Subject analysis set title	main
Subject analysis set type	Per protocol
Subject analysis set description:	
All subjects who where treated according to the protocol	

Primary: duration of complete sensory block to pinprick and time

End point title	duration of complete sensory block to pinprick and time
End point description:	

End point type	Primary
End point timeframe:	
full period	

End point values	Group R	Group RD50	Group RD100	Group RD150
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: hours				
number (not applicable)	8.7	16.4	20.4	21.2

End point values	main			
Subject group type	Subject analysis set			
Number of subjects analysed				
Units: hours				
number (not applicable)	24			

Statistical analyses

Statistical analysis title	Descriptive evaluation of four different groups

Statistical analysis description:

the study was designed as mainly descriptive evaluation of four different study groups. As primary and secondary outcomes consist of time-to-event data, logrank test analyses were performed and the dose-dependency of dexmedetomidine was evaluated with the logrank test for trend. The dose-dependent effects of dexmedetomidine on sedation scores were analysed using the Cuzick trend test. Other data were analysed using a Kruskal–Wallis one-way analysis and unpaired Mann–Whitney U-posthoc test

Comparison groups	Group R v Group RD50 v Group RD100 v Group RD150
Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed models analysis

Adverse events

Adverse events information	
Timeframe for reporting adverse events: from 02.Dec.2013 to 24.Dec.2013	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	18.0
Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Serious adverse events	overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 24 (87.50%)		
Vascular disorders			
Hypotension	Additional description: intermittend Hypotension		
subjects affected / exposed	21 / 24 (87.50%)		
occurrences (all)	21		
Cardiac disorders			
Sinus bradycardia	Additional description: intermittend Sinus bradycardia		
subjects affected / exposed	9 / 24 (37.50%)		
occurrences (all)	9		
Nervous system disorders			
Hypoaesthesia	Additional description: Hypoaesthesia at nerv block site after the end of the study day		
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
Headache			

subjects affected / exposed occurrences (all)	2 / 24 (8.33%) 2		
General disorders and administration site conditions Mucosal dryness subjects affected / exposed occurrences (all)	 7 / 24 (29.17%) 7		

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