Clinical trial results:
DEXAMETHASONE AS ADJUVANT FOR PERIPHERAL NERVE BLOCKADE: A RANDOMIZED, TRIPLE-BLINDED AND CROSSOVER STUDY IN VOLUNTEERS

Summary

EudraCT number	2018-001221-98
Trial protocol	AT
Global end of trial date	16 October 2018

Results information

Result version number	v1 (current)
This version publication date	21 September 2019
First version publication date	21 September 2019

Trial information

Trial identification

Sponsor protocol code	1.3

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	Spitalgasse 23, Vienna, Austria, 1090
Public contact	Daniela Marhofer, Medical University of Vienna, Department of Anaesthesia, Intensive Care and Pain Medicine, +43 14040041030, daniela.marhofer@meduniwien.ac.at
Scientific contact	Daniela Marhofer, Medical University of Vienna, Department of Anaesthesia, Intensive Care and Pain Medicine, +43 14040041030, daniela.marhofer@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	16 November 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 October 2018
Global end of trial reached?	Yes
Global end of trial date	16 October 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the impact of perineural dexamethasone on duration of sensory nerve blockade with clinical testing

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 June 2018
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 recruited by use of the data base of the Dep. of Clinical Pharmacology, Medical University of Vienna.

Pre-assignment

Screening details:

Check of the in- and exclusion criteria, physical examination, vital signs, laboratory assessment and ECG recording

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

Arms

Are arms mutually exclusive?	No
Arm title	Study group 1

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Perineural use

Dosage and administration details:

Ropivacaine 0.75% / perineural Dexamethasone 4mg (= 4ml Ropivacaine 0.56%) & Saline 1ml iv

Arm title	Study group 2

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

4ml Ropivacaine 0.56% & Dexamethasone 4mg iv

Arm title	Study group 3

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Perineural use

Dosage and administration details:

4ml Ropivacaine 0.56% & Saline 1ml iv

Number of subjects in period 1	Study group 1	Study group 2	Study group 3
Started	24	24	24
Completed	24	24	24

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 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	
Gender categorical Units: Subjects			
Female	0	0	
Male	24	24	

End points

End points reporting groups

Reporting group title	Study group 1
Reporting group description: -	
Reporting group title	Study group 2
Reporting group description: -	
Reporting group title	Study group 3
Reporting group description: -	

Primary: To evaluate the impact of perineural dexamethasone on duration of sensory nerve blockade with clinical testing

End point title	To evaluate the impact of perineural dexamethasone on duration of sensory nerve blockade with clinical testing
End point description:	
End point type	Primary
End point timeframe:	
Baseline, 2, 4, 6, 8, 10, 15, 20, 30, 60 min after the block, and then every 30 min until complete recovery.	

End point values	Study group 1	Study group 2	Study group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	24	24	
Units: time/ minutes				
number (not applicable)	24	24	24	

Statistical analyses

Statistical analysis title	Statistics to end point
Comparison groups	Study group 1 v Study group 2 v Study group 3
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.05
Method	t-test, 2-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 22.06.2018-16.10.2018	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.0
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	0		

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

Non-serious adverse events	Overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 24 (12.50%)		
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
General disorders and administration site conditions			
Sickness			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Pain			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Eye disorders			

Erosio corneae subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1		
Gastrointestinal disorders Soft stool subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1		
Infections and infestations Common cold subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 August 2018	Change in patient information sheet

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported