Clinical trial results:
Minimal local anaesthetic volumes for sciatic nerve blockade: A clinical evaluation of ED99 volumes

Summary

EudraCT number	2012-005075-14
Trial protocol	AT
Global end of trial date	09 September 2014

Results information

Result version number	v1 (current)
This version publication date	13 May 2021
First version publication date	13 May 2021

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, Vienn, Austria, 1090
Public contact	Daniela Marhofer, Medizinische Universität Wien, Universitätsklinik für Anästhesie, Allgemeine Intensivmed und Schm, +43 1404004100, daniela.marhofer@meduniwien.ac.at
Scientific contact	Daniela Marhofer, Medizinische Universität Wien, Universitätsklinik für Anästhesie, Allgemeine Intensivmed und Schm, +43 1404004100, 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	02 October 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 September 2014
Global end of trial reached?	Yes
Global end of trial date	09 September 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study is to investigate if the previously evaluated ED99 for ultrasound guided peripheral nerve blockade is transferable for surgical anaesthesia and analgesia.

Protection of trial subjects:

+ Full clinical evaluation of the patients before inclusion in study
+ Perioperative continuous monitoring of vital parameters (blood pressure, ECG, oxygen saturation)
+ Ultrasound guided blockade of the sciatic nerve (real-time)
+ One week after the study, all patients were examined for signs of infection or haematoma.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 November 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 15
Worldwide total number of subjects	15
EEA total number of subjects	15

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)	15
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

After ethical approval, all patients were informed about the nature, scope, procedures, and associated risks of the study. The patients were undergoing foot surgery at the Department of Plastic and Reconstructive Surgery (Medical University of Vienna)

Pre-assignment

Screening details:

Inclusion criteria:surgery in the distribution of the sciatic nerve; age between 18 and 90 years; body mass index < 35 kg.m!2, no legal incapacity, Exclusion criteria:known allergy or hypersensitivity to the study drug; abnormal electrocardiogram (ECG), either atrioventricular block or bradycardia.

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

Arm title	Ropivacain

Arm description:

nclusion criteria:surgery in the distribution of the sciatic nerve; age between 18 and 90 years; body mass index < 35 kg.m!2, no legal incapacity, Exclusion criteria:known allergy or hypersensitivity to the study drug; abnormal electrocardiogram (ECG), either atrioventricular block or bradycardia.

Arm type	Active comparator
Investigational medicinal product name	Ropivacain
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Epidural use

Dosage and administration details:

0,75% extra-epineural Injektion

Number of subjects in period 1	Ropivacain
Started	15
Completed	14
Not completed	1
Lost to follow-up	1

Baseline characteristics

Reporting groups

Reporting group title	Overall Trial

Reporting group description: -

Reporting group values	Overall Trial	Total	
Number of subjects	15	15	
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)	15	15	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	5	5	
Male	10	10	

Subject analysis sets

Subject analysis set title	Ropivacain
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Inclusion criteria:surgery in the distribution of the sciatic nerve; age between 18 and 90 years; body mass index < 35 kg.m!2, no legal incapacity, Exclusion criteria:known allergy or hypersensitivity to the study drug; abnormal electrocardiogram (ECG), either atrioventricular block or bradycardia.

Reporting group values	Ropivacain		
Number of subjects	14		
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)	15		
From 65-84 years	0		
85 years and over	0		

Gender categorical Units: Subjects			
Female	5		
Male	10		

End points

End points reporting groups

Reporting group title	Ropivacain

Reporting group description:

nclusion criteria:surgery in the distribution of the sciatic nerve; age between 18 and 90 years; body mass index < 35 kg.m!2, no legal incapacity, Exclusion criteria:known allergy or hypersensitivity to the study drug; abnormal electrocardiogram (ECG), either atrioventricular block or bradycardia.

Subject analysis set title	Ropivacain
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Inclusion criteria:surgery in the distribution of the sciatic nerve; age between 18 and 90 years; body mass index < 35 kg.m!2, no legal incapacity, Exclusion criteria:known allergy or hypersensitivity to the study drug; abnormal electrocardiogram (ECG), either atrioventricular block or bradycardia.

Primary: surgical analgesia

End point title	surgical analgesia[1]

End point description:

End point type	Primary

End point timeframe:

Sensory and motor block time was defined as the time from performing the block until pinprick < 10% and motor score = 0 (in comparison with the contralateral side)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Sensory and motor block time was defined as the time from performing the block until pinprick < 10%
and motor score = 0 (in comparison with the contralateral side)

End point values	Ropivacain	Ropivacain		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	15	15		
Units: 14	4	4		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

From beginning of the study when performing the block for the operation until 1 week after the intervention/operation

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

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

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 was no Adverse events in this Study

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/25644578