



Clinical trial results:

Regional anaesthesia of the cutaneous nerves of the hip -

A novel ultrasound guided nerve block of the superior cluneal nerves

Summary

EudraCT number	2016-004541-82
Trial protocol	DK
Global end of trial date	22 January 2017

Results information

Result version number	v2 (current)
This version publication date	25 January 2021
First version publication date	02 January 2021
Version creation reason	• Correction of full data set • Correction of p-value

Trial information

Trial identification

Sponsor protocol code	SupClun_1-1
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Palle Juul-Jensens Boulevard 99, Aarhus N, Denmark, 8200
Public contact	Dep. Anaesthesia and Intensive Care, Aarhus University Hospital, +45 28782877, thomas.dahl.nielsen@clin.au.dk
Scientific contact	Dep. Anaesthesia and Intensive Care, Aarhus University Hospital, +45 28782877, thomas.dahl.nielsen@clin.au.dk

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	15 February 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 January 2017
Global end of trial reached?	Yes
Global end of trial date	22 January 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the success of a nerve block of the superior cluneal nerves (SupClun) in producing cutaneous anaesthesia posterior to - and continuous with - the area of anesthesia produced by the lateral femoral cutaneous nerve (LFCN) block and the Transversalis Fascia Plane (TFP) block

Protection of trial subjects:

This volunteer trial was conducted in accordance with the declaration of Helsinki and approved by the Danish Medicines Agency, the Central Denmark Region Committees on health research ethics and the Danish Data Protection Agency. The trial was prospectively registered in the EudraCT database and was monitored by the Good Clinical Practice Unit at Aalborg and Aarhus University Hospitals. Prior to inclusion written informed consent was obtained from all subjects after thorough oral and written participant information had been given.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 January 2017
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	Denmark: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	20
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

Healthy volunteers of 18 years or older were recruited through a Danish website dedicated to recruit volunteers for research. All volunteers received payment for their participation.

Pre-assignment

Screening details:

Inclusion criteria: Age $\geq$ 18 years; Written informed consent; Healthy (ASA I-II); Able to cooperate; Understand and speak Danish

Exclusion criteria: Reduced cutaneous sensibility; anatomy/psychological impediment of participation; allergy to local anesthetics; pregnancy; weight below 65 kg; infection at the site of injection

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Active

Arm description:

15 mL ropivacaine 3.75 mg/mL for superior cluneal nerve block

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

Dosage and administration details:

15 mL 3.75 mg/mL

Arm title	Placebo
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Arm description:

Isotonic saline 15 mL for superior cluneal nerve block.

Arm type	Placebo
Investigational medicinal product name	Sodium chloride 0.9%
Investigational medicinal product code	
Other name	Isotonic saline
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

15 mL isotonic saline for superior cluneal nerve block.

Number of subjects in period 1	Active	Placebo
Started	10	10
Completed	10	10

Baseline characteristics

Reporting groups

Reporting group title	Overall period
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Reporting group description: -

Reporting group values	Overall period	Total	
Number of subjects	20	20	
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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: years			
arithmetic mean	25.3		
standard deviation	± 4.9	-	
Gender categorical			
Units: Subjects			
Female	9	9	
Male	11	11	
ASA score			
American Society of Anesthesiology score			
Units: Subjects			
ASA I	20	20	
ASA II	0	0	
BMI			
Body Mass Index			
Units: kilogram(s)/square meter			
arithmetic mean	22.2		
standard deviation	± 1.9	-	

End points

End points reporting groups

Reporting group title	Active
Reporting group description: 15 mL ropivacaine 3.75 mg/mL for superior cluneal nerve block	
Reporting group title	Placebo
Reporting group description: Isotonic saline 15 mL for superior cluneal nerve block.	

Primary: Success rate of superior cluneal nerve block

End point title	Success rate of superior cluneal nerve block
End point description:	
End point type	Primary
End point timeframe: Pinprick before and 45 min after superior cluneal nerve block	

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: Frequency				
Success	18	0		
Failure	2	20		

Statistical analyses

Statistical analysis title	Success rate of superior cluneal nerve block
Comparison groups	Active v Placebo
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Chi-squared

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

60 minutes after placement of the last nerve block

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	10.0
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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: This was a volunteer study including healthy young volunteers and the interventions were extremely low risk.

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/31061111>