Clinical trial results:
Supraclavicular catheter for regional anesthesia of the shoulder - an explorative study in healthy volunteers.

Summary

EudraCT number	2016-002835-14
Trial protocol	DK
Global end of trial date	24 August 2017

Results information

Result version number	v1 (current)
This version publication date	15 March 2021
First version publication date	15 March 2021

Trial information

Trial identification

Sponsor protocol code	SCCCSH01

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Nordsjællands Hospital
Sponsor organisation address	Dyrehavevej 29, Hillerød, Denmark, 3400
Public contact	Department of anesthesiology, Nordsjællands Hospital Hillerød, kai.henrik.wiborg.lange@regionh.dk
Scientific contact	Department of anesthesiology, Nordsjællands Hospital Hillerød, kai.henrik.wiborg.lange@regionh.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	28 August 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 August 2017
Global end of trial reached?	Yes
Global end of trial date	24 August 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of the trial is to place a supraclavicular catheter in 32 healthy volunteers and examine:
1: If the largest shoulder nerves are affected
2: which other nerves are affected
after injection with a low (5ml) or a high (20 ml) volume of ropivacain 5 mg/ml.

Protection of trial subjects:

Local analgetic skin infiltration before insertion of nerve catheter.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 July 2017
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	Denmark: 32
Worldwide total number of subjects	32
EEA total number of subjects	32

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)	32
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment	
Recruitment details: -	

Pre-assignment	
Screening details: -	

Pre-assignment period milestones	
Number of subjects started	32
Number of subjects completed	32

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, Monitor, Data analyst, Assessor

Arms	
Are arms mutually exclusive?	Yes
Arm title	5 ml Ropivacaine
Arm description: -	
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:

5 ml Ropivacaine 5 mg*ml-1 administered perineurally in relation to the brachial plexus at a supraclavicular level.

Arm title	20 ml ropivacaine
Arm description: -	
Arm type	Active comparator
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:

20 ml Ropivacaine 5 mg*ml-1 administered perineurally in relation to the brachial plexus at a supraclavicular level.

Number of subjects in period 1	5 ml Ropivacaine	20 ml ropivacaine
Started	16	16
Completed	16	16

Baseline characteristics

Reporting groups	
Reporting group title	5 ml Ropivacaine
Reporting group description: -	
Reporting group title	20 ml ropivacaine
Reporting group description: -	

Reporting group values	5 ml Ropivacaine	20 ml ropivacaine	Total
Number of subjects	16	16	32
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	24.7	25.3	
standard deviation	± 8.2	± 3.2	-
Gender categorical Units: Subjects			
Female	9	9	18
Male	7	7	14

End points

End points reporting groups	
Reporting group title	5 ml Ropivacaine
Reporting group description: -	
Reporting group title	20 ml ropivacaine
Reporting group description: -	

Primary: Shoulder nerve block	
End point title	Shoulder nerve block
End point description:	
End point type	Primary
End point timeframe:	
From baseline to T45	

End point values	5 ml Ropivacaine	20 ml ropivacaine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Number	13	15		

Statistical analyses

Statistical analysis title	Shoulder nerves affected
Comparison groups	5 ml Ropivacaine v 20 ml ropivacaine
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Parameter estimate	Risk difference (RD)
Point estimate	-0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.35
upper limit	0.9

Notes:

[1] - Noninferiority margin was based on the lower bound of the 95% confidence interval (CI) for the difference between proportions of succesful shoulder blocks in the 5 ml group vs the 20 ml group being greater than -0.2. As the difference in proportions was above -0.2 and the upper bound of the 95% CI was above zero, our results were inconclusive.

Secondary: Change in spirometry (VC)	
End point title	Change in spirometry (VC)

End point description: The relative change in spirometry (VC) from baseline to 45 minutes after injection of ropivacain 0.5%.	
End point type	Secondary
End point timeframe: T0-T45	

End point values	5 ml Ropivacaine	20 ml ropivacaine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Litres				
arithmetic mean (standard deviation)	-2.6 (± 9.8)	-10.6 (± 8.9)		

Statistical analyses

Statistical analysis title	Change in spirometry (VC)
Comparison groups	5 ml Ropivacaine v 20 ml ropivacaine
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.021
Method	t-test, 2-sided

Secondary: Change in spirometry (FVC)	
End point title	Change in spirometry (FVC)
End point description: The relative change in spirometry (FVC) from baseline to 45 minutes after injection of ropivacain 0.5%.	
End point type	Secondary
End point timeframe: T0-T45	

End point values	5 ml Ropivacaine	20 ml ropivacaine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Litres				
arithmetic mean (standard deviation)	-1.1 (± 8.9)	-6.4 (± 9.3)		

Statistical analyses

Statistical analysis title	Change in spirometry (FVC)
Comparison groups	5 ml Ropivacaine v 20 ml ropivacaine
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.113
Method	t-test, 2-sided

Secondary: Change in spirometry (FEV1)

End point title	Change in spirometry (FEV1)
End point description:	
The relative change in spirometry (FEV1) from baseline to 45 minutes after injection of ropivacain 0.5%.	
End point type	Secondary
End point timeframe:	
T0-T45	

End point values	5 ml Ropivacaine	20 ml ropivacaine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Litres				
arithmetic mean (standard deviation)	-2.7 (± 9.3)	-8.8 (± 7.1)		

Statistical analyses

Statistical analysis title	Change in spirometry (FEV1)
Comparison groups	5 ml Ropivacaine v 20 ml ropivacaine
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.044
Method	t-test, 2-sided

Secondary: Change in spirometry (PEF)

End point title	Change in spirometry (PEF)
End point description:	
The relative change in spirometry (PEF) from baseline to 45 minutes after injection of ropivacain 0.5%.	
End point type	Secondary
End point timeframe:	
T0-T45	

End point values	5 ml Ropivacaine	20 ml ropivacaine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Litres per minute				
arithmetic mean (standard deviation)	0.7 (± 15.4)	-6.7 (± 8.8)		

Statistical analyses

Statistical analysis title	Change in spirometry (PEF)
Comparison groups	5 ml Ropivacaine v 20 ml ropivacaine
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.11
Method	t-test, 2-sided

Secondary: Complete phrenic nerve block

End point title	Complete phrenic nerve block
End point description:	
Number of subjects with a complete unilateral phrenic nerve block defined as a reduction in FVC of at least 20%.	
End point type	Secondary
End point timeframe:	
T0-T45	

End point values	5 ml Ropivacaine	20 ml ropivacaine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Number	0	2		

Statistical analyses

Statistical analysis title	Phrenic nerve block
Comparison groups	5 ml Ropivacaine v 20 ml ropivacaine

Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.14
Method	Chi-squared

Adverse events

Adverse events information	
Timeframe for reporting adverse events: July to september 2017	
Assessment type	Systematic
Dictionary used	
Dictionary name	SNOMED CT
Dictionary version	DK 2015
Reporting groups	
Reporting group title	Adverse events

Reporting group description: -

Serious adverse events	Adverse events		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 32 (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	Adverse events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 32 (3.13%)		
Nervous system disorders			
Subjektiv muskelsvaghed	Additional description: Subjective muscle weakness		
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		

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