



Clinical trial results:

Suprascapular nerve block as postoperative analgesia after arthroscopic shoulder surgery - a randomized, blinded, placebo controlled trial.

Summary

EudraCT number	2015-002391-24
Trial protocol	DK
Global end of trial date	27 August 2018

Results information

Result version number	v1 (current)
This version publication date	26 December 2020
First version publication date	26 December 2020

Trial information

Trial identification

Sponsor protocol code	SSNBCSH01
-----------------------	-----------

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	Kai Henrik Wiborg Lange, Nordsjaellands Hospital, kai.henrik.wiborg.lange@regionh.dk
Scientific contact	Department of Anaesthesiology, Nordsjaellands Hospital, 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	29 August 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 August 2018
Global end of trial reached?	Yes
Global end of trial date	27 August 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this study is to examine the reduction in postoperative pain after arthroscopic shoulder surgery in patients treated with a suprascapular nerve block.

Protection of trial subjects:

Standard postoperative care at the Postoperative Care Unit.

Treatment of pain:

Active Group: Nerve block and PCA-pump with morphine

Placebo Group: PCA-pump with morphine

PCA = Patient-controlled analgesia.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2015
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: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	34
From 65 to 84 years	6

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	40
----------------------------	----

Number of subjects completed	40
------------------------------	----

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, Carer, Assessor
---------------	---

Arms

Are arms mutually exclusive?	Yes
------------------------------	-----

Arm title	Active group
------------------	--------------

Arm description:

Suprascapular nerve block with active drug (Ropivacaine 7.5 mg*ml-1)

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:

Administered perineurally in relation to the suprascapular nerve as a single shot bolus of 5 ml Ropivacaine 7.5 mg*ml-1

Arm title	Placebo group
------------------	---------------

Arm description:

Suprascapular nerve block with placebo (Saline 9 mg*ml-1)

Arm type	Placebo
----------	---------

Investigational medicinal product name	Saline
--	--------

Investigational medicinal product code	
--	--

Other name	
------------	--

Pharmaceutical forms	Solution for injection
----------------------	------------------------

Routes of administration	Perineural use
--------------------------	----------------

Dosage and administration details:

Administered perineurally in relation to the suprascapular nerve as a single shot bolus of 5 ml Saline 9 mg*ml-1

Number of subjects in period 1	Active group	Placebo group
Started	20	20
Completed	20	20

Baseline characteristics

Reporting groups

Reporting group title	Active group
Reporting group description: Suprascapular nerve block with active drug (Ropivacaine 7.5 mg*ml-1)	
Reporting group title	Placebo group
Reporting group description: Suprascapular nerve block with placebo (Saline 9 mg*ml-1)	

Reporting group values	Active group	Placebo group	Total
Number of subjects	20	20	40
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	51.6	54.3	-
standard deviation	± 10.3	± 9.6	-
Gender categorical Units: Subjects			
Female	13	9	22
Male	7	11	18
Height Units: cm			
arithmetic mean	173.1	174.5	-
standard deviation	± 8.3	± 11.2	-
Weight Units: kg			
arithmetic mean	84.7	88.6	-
standard deviation	± 13.3	± 19.1	-

End points

End points reporting groups

Reporting group title	Active group
Reporting group description:	
Suprascapular nerve block with active drug (Ropivacaine 7.5 mg*ml-1)	
Reporting group title	Placebo group
Reporting group description:	
Suprascapular nerve block with placebo (Saline 9 mg*ml-1)	

Primary: VAS reduction at T30

End point title	VAS reduction at T30
End point description:	
Change in pain score (VAS 0-100mm) from baseline to T30 (30 minutes after application of nerve block)	
End point type	Primary
End point timeframe:	
From Baseline to T30	

End point values	Active group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: VAS				
arithmetic mean (standard deviation)	-50.2 (± 17.9)	-26.8 (± 9.9)		

Statistical analyses

Statistical analysis title	VAS score reduction from baseline to T30
Comparison groups	Active group v Placebo group
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	t-test, 2-sided

Secondary: VAS AUC T30-T360 during maximum abduction

End point title	VAS AUC T30-T360 during maximum abduction
End point description:	
VAS score at maximum active abduction of the shoulder ½-6 hours after injection measured as area under the curve (T30-T360; AUC)	
End point type	Secondary

End point timeframe:

From T30-T360

End point values	Active group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: VAS				
arithmetic mean (standard deviation)	134.0 (± 133.3)	229.1 (± 93.4)		

Statistical analyses

Statistical analysis title	AUC T30-T360 abduction
Comparison groups	Active group v Placebo group
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.013
Method	t-test, 2-sided

Secondary: AUC T30-T360 at rest

End point title	AUC T30-T360 at rest
End point description:	VAS score at maximum active abduction of the shoulder ½-6 hours after injection measured as area under the curve (T30-T360; AUC)
End point type	Secondary
End point timeframe:	T30-T360

End point values	Active group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: VAS				
arithmetic mean (standard deviation)	59.5 (± 80.2)	134.6 (± 92.0)		

Statistical analyses

Statistical analysis title	AUC T30-T360 rest
Comparison groups	Active group v Placebo group
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01
Method	t-test, 2-sided

Secondary: Total morphine usage T0-T360

End point title	Total morphine usage T0-T360
End point description:	Total use of morphine from 0-6 hours after injection (T0-T360)
End point type	Secondary
End point timeframe:	T0-T360

End point values	Active group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: mg				
arithmetic mean (standard deviation)	6.5 (± 8.4)	18.5 (± 15.7)		

Statistical analyses

Statistical analysis title	Morphine T0-T360
Comparison groups	Active group v Placebo group
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01
Method	t-test, 2-sided

Secondary: Change in infraspinatus sEMG from baseline to T30

End point title	Change in infraspinatus sEMG from baseline to T30
End point description:	Change in activity of the infraspinatus muscle during maximum voluntary isometric contraction from baseline to T30 measured with surface EMG (sEMG)
End point type	Secondary
End point timeframe:	From baseline to 30 minutes after injection (T30)

End point values	Active group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[1]	0 ^[2]		
Units: mV				
arithmetic mean (standard deviation)	()	()		

Notes:

[1] - sEMG signals too poor to analyze

[2] - sEMG signals too poor to analyze

Statistical analyses

No statistical analyses for this end point

Secondary: Change in external rotation shoulder strength from baseline to T30

End point title	Change in external rotation shoulder strength from baseline to T30
End point description:	Percentage change in maximum voluntary isometric contraction during external rotation of the shoulder from baseline to 30 minutes after injection (T30) measured with a handheld dynamometer.
End point type	Secondary
End point timeframe:	From baseline measurements to 30 minutes after injection (T30)

End point values	Active group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: mV				
arithmetic mean (standard deviation)	-68.9 (± 26.9)	9.1 (± 23.0)		

Statistical analyses

Statistical analysis title	Change in external rotation strength T0-T30
Comparison groups	Active group v Placebo group
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	t-test, 2-sided

Secondary: Change in abduction shoulder strength from baseline to T30

End point title	Change in abduction shoulder strength from baseline to T30
End point description:	Percentage change in maximum voluntary isometric contraction during abduction of the shoulder from baseline to 30 minutes after injection (T30) measured with a handheld dynamometer.
End point type	Secondary
End point timeframe:	From baseline to T30

End point values	Active group	Placebo group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: mV				
arithmetic mean (standard deviation)	-18.9 (± 44.9)	27.9 (± 37.4)		

Statistical analyses

Statistical analysis title	Change in abduction strength T0-T30
Comparison groups	Active group v Placebo group
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	t-test, 2-sided

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

24th november 2015 - 27th august 2018

Assessment type Systematic

Dictionary used

Dictionary name SNOMED CT

Dictionary version DK 2015

Reporting groups

Reporting group title Ropivacaine 7.5 mg*ml-1

Reporting group description: -

Reporting group title Saline 9 mg*ml-1

Reporting group description: -

Serious adverse events	Ropivacaine 7.5 mg*ml-1	Saline 9 mg*ml-1	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Ropivacaine 7.5 mg*ml-1	Saline 9 mg*ml-1	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	

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: No non-serious adverse events recorded during the study period.

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Unable to analyze surface electromyography (sEMG) data due to very poor sEMG signals.

Notes: