Clinical trial results:
Effect of a lateral nerve of the thigh block on post-operative pain among patients with pain (VAS>40mm) during flexion of the hip the first or second postoperative day

Summary

EudraCT number	2014-003730-10
Trial protocol	DK
Global end of trial date	21 September 2015

Results information

Result version number	v1 (current)
This version publication date	17 August 2017
First version publication date	17 August 2017

Trial information

Trial identification

Sponsor protocol code	001-2014-KHTY

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02344264
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Department of Anesthesiology, Næstved Hospital
Sponsor organisation address	Ringstedgade 61, Næstved, Denmark, 4700
Public contact	Daniel Hägi-Pedersen, Department of Anesthesiology, Næstved Hospital, +45 56514792, dhag@regionsjaelland.dk
Scientific contact	Daniel Hägi-Pedersen, Department of Anesthesiology, Næstved Hospital, +45 56514792, dhag@regionsjaelland.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	21 October 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 September 2015
Global end of trial reached?	Yes
Global end of trial date	21 September 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Effect of a lateral cutaneuos nerve block in patient with moderat to severe pain after total hip replacement surgery during active flexion af the hip the first or second postoperative day. VAS score.

Protection of trial subjects:

Treated with usual care.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 January 2015
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: 60
Worldwide total number of subjects	60
EEA total number of subjects	60

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)	21
From 65 to 84 years	39
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:
All patients, which underwent a primary total hip replacement

Pre-assignment period milestones

Number of subjects started	60
Number of subjects completed	60

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, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Group A

Arm description:
First blockade: ropivacaine 7,5mg/ml 8 ml second blockade: placebo: saline 8 ml

Arm type	Cross-reference
Investigational medicinal product name	ropivacaine
Investigational medicinal product code	
Other name	naropin
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:
60 milligrams

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:
8 milliliters

Arm title	Group B

Arm description:
First blockade: placebo: saline 8 ml second blockade: ropivacaine 7,5mg/ml 8 ml

Arm type	Cross-reference
Investigational medicinal product name	ropivacaine
Investigational medicinal product code	
Other name	naropin
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details: 60 milligrams	
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:
8 milliliters

Number of subjects in period 1	Group A	Group B
Started	30	30
Completed	30	30

Baseline characteristics

End points

End points reporting groups	
Reporting group title	Group A
Reporting group description:	
First blockade: ropivacaine 7,5mg/ml 8 ml second blockade: placebo: saline 8 ml	
Reporting group title	Group B
Reporting group description:	
First blockade: placebo: saline 8 ml second blockade: ropivacaine 7,5mg/ml 8 ml	

Primary: Difference in VAS between NCFL and placebo during active 30 degrees hip flexion	
End point title	Difference in VAS between NCFL and placebo during active 30 degrees hip flexion
End point description:	
End point type	Primary
End point timeframe:	
45 minutes	

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: millimeter(s)				
median (inter-quartile range (Q1-Q3))	35 (32 to 53)	61.5 (44 to 72)		

Statistical analyses

Statistical analysis title	Hodges-lehmann-estimator
Comparison groups	Group A v Group B
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Hodges-lehmann-estimator
Parameter estimate	Median difference (final values)
Point estimate	-17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31
upper limit	-4

Variability estimate	Standard deviation

Secondary: Difference in mean VAS between the groups during active hip flexion 15 minutes

End point title	Difference in mean VAS between the groups during active hip flexion 15 minutes

End point description:

End point type	Secondary

End point timeframe:

15 minutes

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: millimeter(s)				
median (inter-quartile range (Q1-Q3))	39.5 (29.25 to 55.25)	58.5 (39 to 71.25)		

Statistical analyses

Statistical analysis title	Hodges-lehmann-estimator
Comparison groups	Group B v Group A
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Hodges-lehmann-estimator
Parameter estimate	Median difference (final values)
Point estimate	-16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26
upper limit	-5
Variability estimate	Standard deviation

Secondary: Difference in mean VAS between the groups during active hip flexion 30 minutes

End point title	Difference in mean VAS between the groups during active hip flexion 30 minutes

End point description:

End point type	Secondary
End point timeframe:	
30 minutes	

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: millimeter(s)				
median (inter-quartile range (Q1-Q3))	44 (24.25 to 57)	58.5 (38.75 to 70.25)		

Statistical analyses

Statistical analysis title	Hodges-lehmann-estimator
Comparison groups	Group A v Group B
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Hodges-lehmann-estimator
Parameter estimate	Median difference (final values)
Point estimate	-13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24
upper limit	0
Variability estimate	Standard deviation

Secondary: Difference in mean VAS between the groups during active hip flexion 60 minutes

End point title	Difference in mean VAS between the groups during active hip flexion 60 minutes
End point description:	

End point type	Secondary
End point timeframe:	
60 minutes	

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: millimeter(s)				
median (inter-quartile range (Q1-Q3))	34 (18.75 to 50)	55 (24.75 to 70.5)		

Statistical analyses

Statistical analysis title	Hodges-lehmann-estimator
Comparison groups	Group A v Group B
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Hodges-lehmann-estimator
Parameter estimate	Median difference (final values)
Point estimate	-17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30
upper limit	-5
Variability estimate	Standard deviation

Secondary: Difference in mean VAS between the groups during active hip flexion 75 minutes

End point title	Difference in mean VAS between the groups during active hip flexion 75 minutes

End point description:

End point type	Secondary

End point timeframe:

75 minutes

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	29		
Units: millimeter(s)				
median (inter-quartile range (Q1-Q3))	35.5 (18 to 53.5)	49 (22.5 to 66)		

Statistical analyses

Statistical analysis title	Hodges-lehmann-estimator
Comparison groups	Group A v Group B
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Hodges-lehmann-estimator
Parameter estimate	Median difference (final values)
Point estimate	-9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23
upper limit	6
Variability estimate	Standard deviation

Secondary: Difference in mean VAS between the groups during active hip flexion 90 minutes

End point title	Difference in mean VAS between the groups during active hip flexion 90 minutes
End point description:	
End point type	Secondary
End point timeframe:	
90 minutes	

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	29		
Units: millimeter(s)				
median (inter-quartile range (Q1-Q3))	34.5 (15 to 51.25)	50 (22.5 to 65)		

Statistical analyses

Statistical analysis title	Hodges-lehmann-estimator
Comparison groups	Group A v Group B

Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Hodges-lehmann-estimator
Parameter estimate	Median difference (final values)
Point estimate	-10
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25
upper limit	5
Variability estimate	Standard deviation

Secondary: Difference in mean VAS between the groups at rest 15 minutes

End point title	Difference in mean VAS between the groups at rest 15 minutes
End point description:	
End point type	Secondary
End point timeframe: 15 minutes	

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: millimeter(s)				
median (inter-quartile range (Q1-Q3))	30.5 (14.25 to 45)	37.5 (12 to 57.5)		

Statistical analyses

Statistical analysis title	Hodges-lehmann-estimator
Comparison groups	Group A v Group B
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Hodges-lehmann-estimator
Parameter estimate	Median difference (final values)
Point estimate	-5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-17
upper limit	8
Variability estimate	Standard deviation

Secondary: Difference in mean VAS between the groups at rest 30 minutes

End point title	Difference in mean VAS between the groups at rest 30 minutes
End point description:	
End point type	Secondary
End point timeframe: 30 minutes	

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: millimeter(s)				
median (inter-quartile range (Q1-Q3))	32 (14 to 41.75)	37 (10 to 59.75)		

Statistical analyses

Statistical analysis title	Hodges-lehmann-estimator
Comparison groups	Group A v Group B
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Hodges-lehmann-estimator
Parameter estimate	Median difference (final values)
Point estimate	-6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20
upper limit	6
Variability estimate	Standard deviation

Secondary: Difference in mean VAS between the groups at rest 45 minutes

End point title	Difference in mean VAS between the groups at rest 45 minutes

End point description:

End point type	Secondary

End point timeframe:

45 minutes

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: millimeter(s)				
median (inter-quartile range (Q1-Q3))	22.5 (9 to 39.25)	37.5 (10.75 to 62.5)		

Statistical analyses

Statistical analysis title	Hodges-lehmann-estimator
Comparison groups	Group A v Group B
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Hodges-lehmann-estimator
Parameter estimate	Median difference (final values)
Point estimate	-10
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24
upper limit	4
Variability estimate	Standard deviation

Secondary: Difference in mean VAS between the groups at rest 60 minutes

End point title	Difference in mean VAS between the groups at rest 60 minutes

End point description:

End point type	Secondary

End point timeframe:

60 minutes

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: millimeter(s)				
median (inter-quartile range (Q1-Q3))	17.5 (9 to 32.5)	28 (4 to 52)		

Statistical analyses

Statistical analysis title	Hodges-lehmann-estimator
Comparison groups	Group A v Group B
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Hodges-lehmann-estimator
Parameter estimate	Median difference (final values)
Point estimate	-6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20
upper limit	4
Variability estimate	Standard deviation

Secondary: Difference in mean VAS between the groups at rest 75 minutes

End point title	Difference in mean VAS between the groups at rest 75 minutes

End point description:

End point type	Secondary

End point timeframe:

75 minutes

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	29		
Units: millimeter(s)				
median (inter-quartile range (Q1-Q3))	15 (5 to 32)	25 (4.5 to 46.5)		

Statistical analyses

Statistical analysis title	Hodges-lehmann-estimator
Comparison groups	Group A v Group B
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Hodges-lehmann-estimator
Parameter estimate	Median difference (final values)
Point estimate	-4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18
upper limit	5
Variability estimate	Standard deviation

Secondary: Difference in mean VAS between the groups at rest 90 minutes

End point title	Difference in mean VAS between the groups at rest 90 minutes
End point description:	
End point type	Secondary
End point timeframe:	
90 minutes	

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	29		
Units: millimeter(s)				
median (inter-quartile range (Q1-Q3))	15 (5 to 30.25)	25 (1 to 42.5)		

Statistical analyses

Statistical analysis title	Hodges-lehmann-estimator
Comparison groups	Group A v Group B
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Hodges-lehmann-estimator
Parameter estimate	Mean difference (final values)
Point estimate	-5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-19
upper limit	5
Variability estimate	Standard deviation

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 12 hours after first injection	
Assessment type	Systematic

Dictionary used	
Dictionary name	ICH Guideline
Dictionary version	E6

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

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: Only adverse events related to the study medication were included.

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