Clinical trial results:
Effect of a lateral nerve of the thigh block on postoperative pain after total hip replacement surgery: a clinical radomised trial.

Summary

EudraCT number	2013-004501-12
Trial protocol	DK
Global end of trial date	01 October 2014

Results information

Result version number	v1 (current)
This version publication date	16 August 2017
First version publication date	16 August 2017

Trial information

Trial identification

Sponsor protocol code	001-2013

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02289937
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Departement of Anesthesiology, Næstved Hospital
Sponsor organisation address	Ringstedgade 61, Næstved, Denmark, 4700
Public contact	Daniel Hägi-Pedersen, Departement of Anesthesiology, Næstved Hospital, +45 56514792, dhag@regionsjaelland.dk
Scientific contact	Daniel Hägi-Pedersen, Departement 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	20 February 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 October 2014
Global end of trial reached?	Yes
Global end of trial date	01 October 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Investigation of the influence of a lateral cutaneus nerve of the thigh block on postoperative pain after total hip replacement surgery with visual analog scale and on the total oxynorm dose 1. day after surgery.

Protection of trial subjects:

Treated with usual care.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 March 2014
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: 100
Worldwide total number of subjects	100
EEA total number of subjects	100

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)	25
From 65 to 84 years	71
85 years and over	4

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

All patients planned for primary total hip replacement

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	Ropivacaine

Arm description:

8 ml of ropivacaine 7,5 mg/ml will be injected around nervus cutaneous femoral lateralis. Ultrasound-guided.

Arm type	Experimental
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

Arm title	Placebo

Arm description:

8 ml of isotonic saline will be injected around nervus cutaneous femoral lateralis. Ultrasound-guided

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:

8 milliliters

Number of subjects in period 1	Ropivacaine	Placebo
Started	47	53
Completed	47	53

Baseline characteristics

End points

End points reporting groups

Reporting group title	Ropivacaine
Reporting group description:	
8 ml of ropivacaine 7,5 mg/ml will be injected around nervus cutaneous femoral lateralis. Ultrasound-guided.	
Reporting group title	Placebo
Reporting group description:	
8 ml of isotonic saline will be injected around nervus cutaneous femoral lateralis. Ultrasound-guided	

Primary: VAS-score 4 hours postoperative during movement

End point title	VAS-score 4 hours postoperative during movement
End point description:	
End point type	Primary
End point timeframe:	
4 hours postoperative	

End point values	Ropivacaine	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	53		
Units: mm				
median (inter-quartile range (Q1-Q3))	26.5 (13.5 to 40)	31 (18 to 50)		

Statistical analyses

Statistical analysis title	Mann-Withney-U-Test
Comparison groups	Ropivacaine v Placebo
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)

Secondary: Oxycodone consumed the first 24 h

End point title	Oxycodone consumed the first 24 h
End point description:	
End point type	Secondary

End point timeframe:

0-24 hours postoperatively

End point values	Ropivacaine	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	53		
Units: milligram(s)				
median (inter-quartile range (Q1-Q3))	7 (2 to 13)	6 (2 to 9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to first oxynorm requirement

End point title	Time to first oxynorm requirement

End point description:

End point type	Secondary

End point timeframe:

0-24 hours postoperatively

End point values	Ropivacaine	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	53		
Units: minute				
median (inter-quartile range (Q1-Q3))	253 (144 to 379)	237 (155 to 380)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cumulated ambulation score the first day

End point title	Cumulated ambulation score the first day

End point description:

Ability to mobilize judged by the cumulated ambulation (CAS) score: 0-6; 0 no mobilization, 6: fully mobilized

End point type	Secondary

End point timeframe:

0-24 hours postoperatively

End point values	Ropivacaine	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	43		
Units: score				
median (inter-quartile range (Q1-Q3))	5 (3 to 6)	5 (4 to 6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time from surgery to first ambulation

End point title	Time from surgery to first ambulation
End point description: Time to first mobilization	
End point type	Secondary
End point timeframe: 0-24 hours postoperatively	

End point values	Ropivacaine	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	53		
Units: minute				
median (inter-quartile range (Q1-Q3))	368 (330 to 519)	420 (364 to 470)		

Statistical analyses

No statistical analyses for this end point

Secondary: Length of hospital stay

End point title	Length of hospital stay
End point description:	
End point type	Secondary
End point timeframe: 0-7 days postoperative	

End point values	Ropivacaine	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	53		
Units: hour				
arithmetic mean (standard deviation)	49 (± 10)	50 (± 20)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 0-24 hours postoperatively	
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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/27006014