Clinical trial results:
A randomized trial of automated intermittent ropivacaine administration vs. continuous infusion in an interscalene catheter

Summary

EudraCT number	2013-000235-27
Trial protocol	DK
Global end of trial date	22 March 2015

Results information

Result version number	v1 (current)
This version publication date	25 March 2021
First version publication date	25 March 2021

Trial information

Trial identification

Sponsor protocol code	2013-000235-27

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Odense Universitets hospital
Sponsor organisation address	J. B. Winsløws Vej 4, Odense, Denmark, 5000
Public contact	Dep. V, Odense University Hospital, 45 66113333,
Scientific contact	Dep. V, Odense University Hospital, 45 66113333,

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	04 April 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 March 2015
Global end of trial reached?	Yes
Global end of trial date	22 March 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigater wether we can reduce pain associated with shoulder surgery by changing the adminitration af local anaesthetic in an interscalene catheter from continuous infusion to intermittent bolus injection

Protection of trial subjects:

Written informed consent was obtained from all subjects before enrollment. The investigators performed this.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 February 2013
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: 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)	20
From 65 to 84 years	40
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Written informed consent was obtained from all subjects before enrollment. The investigators performed this.

Pre-assignment

Screening details:

Patients were recruited in the Department of Orthopedic Surgery, Odense University Hospi- tal, Denmark.
Inclusion criteria:
Adult patients (aged ≥ 18 years, ASA 1-3)
undergoing major shoulder surgery performed under general anesthesia with continuous inter- scalene nerve block.

Pre-assignment period milestones

Number of subjects started	35[1]
Number of subjects completed	35

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 10 more patients were enrolled to ensure statistical significance

Period 1

Period 1 title	Study period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Data analyst, Carer, Assessor

Arms

Arm title	intervention

Arm description:

ropivacain administation

Arm type	Experimental
Investigational medicinal product name	ropivacain
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for suspension for injection
Routes of administration	Infiltration

Dosage and administration details:

2mg/ml 16ml/t

Number of subjects in period 1[2]	intervention
Started	35
Completed	35

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 10 more patients were enrolled to ensure statistical significance

Period 2

Period 2 title	intervention
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Data analyst, Carer, Assessor, Subject

Arms

Arm title	intervention

Arm description:

control

Arm type	Placebo
Investigational medicinal product name	saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Infiltration

Dosage and administration details:

16ml/t

Number of subjects in period 2	intervention
Started	35
Completed	35

Baseline characteristics

Reporting groups

Reporting group title	Study period

Reporting group description: -

Reporting group values	Study period	Total	
Number of subjects	35	35	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	15	15	
From 65-84 years	20	20	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	11	11	
Male	24	24	
VAS			
VAS 1-10			
Units: Subjects			
VAS	20	20	
morphine	15	15	
Control			
Placebo saline			
Units: ml			
median	1		
standard deviation	± 1	-	

Subject analysis sets

Subject analysis set title	control
Subject analysis set type	Full analysis
Subject analysis set description: placebo was administered (saline)	
Subject analysis set title	intervention
Subject analysis set type	Full analysis
Subject analysis set description: ropivacain	

Reporting group values	control	intervention	
Number of subjects	35	35	
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)	15		
From 65-84 years	20		
85 years and over	0		
Gender categorical Units: Subjects			
Female	17		
Male	18		
VAS			
VAS 1-10			
Units: Subjects			
VAS	35		
morphine	35		
Control			
Placebo saline			
Units: ml			
median	1		
standard deviation	± 1	±	

End points

End points reporting groups

Reporting group title	intervention
Reporting group description: ropivacain administation	
Reporting group title	intervention
Reporting group description: control	
Subject analysis set title	control
Subject analysis set type	Full analysis
Subject analysis set description: placebo was administered (saline)	
Subject analysis set title	intervention
Subject analysis set type	Full analysis
Subject analysis set description: ropivacain	

Primary: VAS

End point title	VAS[1]
End point description: VAS score from 1-10	
End point type	Primary
End point timeframe: Through out the study period	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: due to technical complication it was not possible to assign a statistical analysis it can be viewed en the article

End point values	intervention			
Subject group type	Reporting group			
Number of subjects analysed	35			
Units: mg				
number (not applicable)				
VAS	2.9			

Statistical analyses

No statistical analyses for this end point

Secondary: morphine

End point title	morphine
End point description:	
End point type	Secondary

End point timeframe:
through out the study

End point values	intervention	intervention	control	intervention
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	35	35	35	
Units: mg				
medication	35	35	35	35

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: Through out the study	
Adverse event reporting additional description: one patient experienced a lung embolism during the study period.	
Assessment type	Systematic

Dictionary used

Dictionary name	Danish medcal center
Dictionary version	1

Reporting groups

Reporting group title	study group
Reporting group description: included patients	

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 is right

Serious adverse events	study group		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Vascular disorders			
Lung embolism	Additional description: One patient experienced a lung embolism during the study period was not considered in relation to the study		
subjects affected / exposed	1 / 1 (100.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	study group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		

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.

VAS might not be the best measure for effect

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/29034961