Clinical trial results:
Does perineural dexmedetomidine prolong the duration of an adductor canal block when controlling for a systemic effect? - a randomized, blinded, paired study in healthy volunteers

Summary

EudraCT number	2014-005651-89
Trial protocol	DK
Global end of trial date	09 September 2015

Results information

Result version number	v1 (current)
This version publication date	22 December 2021
First version publication date	22 December 2021

Trial information

Trial identification

Sponsor protocol code	SM2-JH-2014

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Zealand University Hospital
Sponsor organisation address	Lykkebækvej 1, Koege, Denmark, 4600
Public contact	Clinical trials information, Køge Sygehus, 0045 60610666, hessel@dadlnet.dk
Scientific contact	Clinical trials information, Køge Sygehus, 0045 60610666, hessel@dadlnet.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	01 October 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 September 2015
Global end of trial reached?	Yes
Global end of trial date	09 September 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate whether dexmedetomidine as an adjuvant to ropivacaine for adductor canal block increases duration of the sensory block when controlling for a systemic effect

Protection of trial subjects:

All nerve blocks were performed by a trained anesthesiologist

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 May 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: 42
Worldwide total number of subjects	42
EEA total number of subjects	42

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)	42
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

PAtients very healthy volunteers recruited in the medical School of Copenhagens medical bulletin.

Pre-assignment

Screening details:

Eligible volunteers were males, more than 18 years old, and
had American Society of Anesthesiologists physical status I.
Exclusion criteria were inability to read and speak Danish,
allergies to the involved drugs, weekly alcohol consumption of more than 21 units, medical abuse, use of any analgesics
within 48 h or consumption of opioids within

Period 1

Period 1 title	baseline
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	Ropi + dex

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Dexmedetomidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Perineural use

Dosage and administration details:

100ug perineurally

Arm title	Ropi + placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Perineural use

Dosage and administration details:

1ml

Number of subjects in period 1	Ropi + dex	Ropi + placebo
Started	21	21
Completed	21	21

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

Arms	
Are arms mutually exclusive?	Yes
Arm title	Ropi + placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	ropivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Perineural use
Dosage and administration details: 150mg	
Arm title	Ropi + dex
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Dexmedetomidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Perineural use
Dosage and administration details: 100ug	

Number of subjects in period 2	Ropi + placebo	Ropi + dex
Started	21	21
Completed	21	21

Baseline characteristics

Reporting groups	
Reporting group title	baseline

Reporting group description: -

Reporting group values	baseline	Total	
Number of subjects	42	42	
Age categorical Units: Subjects			
Age continuous Units: years median full range (min-max)	 23 19 to 27	 -	
Gender categorical Units: Subjects			
Female	0	0	
Male	42	42	

End points

End points reporting groups

Reporting group title	Ropi + dex
Reporting group description: -	
Reporting group title	Ropi + placebo
Reporting group description: -	
Reporting group title	Ropi + placebo
Reporting group description: -	
Reporting group title	Ropi + dex
Reporting group description: -	

Primary: duration of sensory nerve block assessed by temperature discrimination

End point title	duration of sensory nerve block assessed by temperature discrimination
End point description:	
End point type	Primary
End point timeframe: 0-48h	

End point values	Ropi + placebo	Ropi + dex		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	21		
Units: hours				
arithmetic mean (confidence interval 95%)	20 (19 to 21)	22 (21 to 23)		

Statistical analyses

Statistical analysis title	paired t test
Statistical analysis description: paired t test	
Comparison groups	Ropi + placebo v Ropi + dex
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.05
Method	t-test, 2-sided

Secondary: duration of sensory nerve block assessed by pinprick

End point title	duration of sensory nerve block assessed by pinprick

End point description:

End point type	Secondary

End point timeframe:

0-48h

End point values	Ropi + placebo	Ropi + dex		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	21		
Units: hours				
arithmetic mean (confidence interval 95%)	20 (19 to 21)	22 (21 to 23)		

Statistical analyses

No statistical analyses for this end point

Secondary: duration of sensory nerve block assessed pain during tonic heat stimulation

End point title	duration of sensory nerve block assessed pain during tonic heat stimulation

End point description:

End point type	Secondary

End point timeframe:

0-48h

End point values	Ropi + placebo	Ropi + dex		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	21		
Units: hours				
arithmetic mean (confidence interval 95%)	20 (19 to 21)	22 (21 to 23)		

Statistical analyses

No statistical analyses for this end point

Secondary: duration of nerve block assessed by warmth detection threshold

End point title	duration of nerve block assessed by warmth detection threshold

End point description:

End point type	Secondary

End point timeframe:

0-48h

End point values	Ropi + placebo	Ropi + dex		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	21		
Units: hours				
arithmetic mean (confidence interval 95%)	21 (20 to 22)	23 (21 to 24)		

Statistical analyses

No statistical analyses for this end point

Secondary: duration of sensory nerve block assessed by heat pain detection threshold

End point title	duration of sensory nerve block assessed by heat pain detection threshold

End point description:

End point type	Secondary

End point timeframe:

0-48

End point values	Ropi + placebo	Ropi + dex		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	21		
Units: hours				
arithmetic mean (confidence interval 95%)	20 (19 to 21)	21 (20 to 22)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 0-48 h	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	1
Reporting groups	
Reporting group title	all participants

Reporting group description: -

Serious adverse events	all participants		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 42 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	all participants		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 42 (4.76%)		
Cardiac disorders			
Bradycardia	Additional description: bradycardia requiring medical treatment		
subjects affected / exposed	2 / 42 (4.76%)		
occurrences (all)	2		

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