Clinical trial results:
The influence of different doses of local anaesthetics on the sensory distribution of lateral femoral cutaneous nerve block - a randomised, blinded, paired trial in heathy volunteers

Summary

EudraCT number	2016-004936-39
Trial protocol	DK
Global end of trial date	09 June 2017

Results information

Result version number	v1
This version publication date	07 January 2021
First version publication date	07 January 2021

Trial information

Trial identification

Sponsor protocol code	SM2-KHT-2016

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03138668
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Department of Anesthesiology
Sponsor organisation address	Ringstedgade 61, Næstved, Denmark, 4700
Public contact	Office, Department of Anesthesiology, Næstved Hospital, 45 56514002, anaestesisekretariat@regionsjaelland.dk
Scientific contact	Office, Department of Anesthesiology, Næstved Hospital, 45 56514002, anaestesisekretariat@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	09 June 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 June 2017
Global end of trial reached?	Yes
Global end of trial date	09 June 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the sensory distribution of a LFCN-block with two different doses

Protection of trial subjects:

The participants were healthy volanteers. Each participant got to blocks, one on each side. There were not taken special measurments regarding pain, as, local anesthesia at the point of injection also would create pain.
The sourroundings however where kept quite, and participants had privacy.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 May 2017
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: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

50 paritcipants were assessed for eligibility, 30 participants were excluded due to not meeting inclusion criteria, not eligible for study dates, declined participation

Pre-assignment period milestones

Number of subjects started	20
Number of subjects completed	20

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, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Group A

Arm description:

LFCN-block with 8 mL ropivacaine 0.75% on their right side and a LFCN-block containing 16 mL ropivacaine 0.75% on the left side.

Arm type	Active comparator
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:

Dosage 60 mg or 120 mg, given perineural at the lateral femoral cutaneous nerve.

Arm title	Group B

Arm description:

LFCN-block with 16 mL ropivacaine 0.75% on their right side and a LFCN-block containing 8 mL ropivacaine 0.75% on the left side.

Arm type	Active comparator
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:

Dosage 60 mg or 120 mg, given perineural at the lateral femoral cutaneous nerve.

Number of subjects in period 1	Group A	Group B
Started	11	9
Completed	11	9

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	20	20	
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)	20	20	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	25		
full range (min-max)	19 to 49	-	
Gender categorical Units: Subjects			
Female	7	7	
Male	13	13	
Height Units: cm			
arithmetic mean	176		
full range (min-max)	164 to 186	-	
Weight Units: kg			
arithmetic mean	70		
full range (min-max)	55 to 85	-	
Quadriceps femoris, MVIC, right leg			
Maximum Voluntary Isometric Contraction of quadriceps femoris			
Units: kg			
arithmetic mean	41		
full range (min-max)	26 to 58	-	
Quadriceps femoris, MVIC, left leg			
Maximum Voluntary Isometric Contraction of quadriceps femoris			
Units: kg			
arithmetic mean	44		
full range (min-max)	26 to 63	-	
Heat stimulation, VAS, right leg			
Visual Analogue Score of pain during heat stimulation.			

Units: mm			
arithmetic mean	41		
full range (min-max)	9 to 96	-	
Heat stimulation, VAS, left leg			
Visual Analogue Score of pain during heat stimulation.			
Units: mm			
arithmetic mean	44		
full range (min-max)	11 to 94	-	

End points

End points reporting groups

Reporting group title	Group A
Reporting group description:	
LFCN-block with 8 mL ropivacaine 0.75% on their right side and a LFCN-block containing 16 mL ropivacaine 0.75% on the left side.	
Reporting group title	Group B
Reporting group description:	
LFCN-block with 16 mL ropivacaine 0.75% on their right side and a LFCN-block containing 8 mL ropivacaine 0.75% on the left side.	

Primary: Coverage of posterior incision by temperature discrimination test

End point title	Coverage of posterior incision by temperature discrimination test
End point description:	
End point type	Primary
End point timeframe:	
One hour post block	

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	9		
Units: percent				
median (inter-quartile range (Q1-Q3))	0 (0 to 0)	0 (0 to 0)		

Statistical analyses

Statistical analysis title	Difference of Coverage of post incision by temp
Statistical analysis description:	
Diffence of the coverage of posterior incision by temperature discrimination test.	
Comparison groups	Group A v Group B
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.345
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Mean difference (final values)
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	3.5

Secondary: Coverage of lateral incision by temperature discrimination test

End point title	Coverage of lateral incision by temperature discrimination test
End point description:	
End point type	Secondary
End point timeframe:	
One hour post block	

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	9		
Units: percent				
median (inter-quartile range (Q1-Q3))	0 (0 to 19.3)	19.5 (0 to 45.3)		

Statistical analyses

Statistical analysis title	Difference of Coverage of lateral incision by temp
Statistical analysis description:	
Diffence of the coverage of lateral incision by temperature discrimination test.	
Comparison groups	Group A v Group B
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.221
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Median difference (final values)
Point estimate	7.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.6
upper limit	24.5

Secondary: Coverage of posterior incision by mechanical discrimination test

End point title	Coverage of posterior incision by mechanical discrimination test

End point description:

End point type	Secondary

End point timeframe:

One hour post block

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	9		
Units: percent				
median (inter-quartile range (Q1-Q3))	0 (0 to 0)	0 (0 to 0)		

Statistical analyses

Statistical analysis title	Difference of Coverage of post incision by mech

Statistical analysis description:

Diffence of the coverage of posterior incision by mechanical discrimination test.

Comparison groups	Group A v Group B
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.715
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Median difference (final values)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Secondary: Coverage of lateral incision by mechanical discrimination test

End point title	Coverage of lateral incision by mechanical discrimination test

End point description:

End point type	Secondary

End point timeframe:

On hour post block.

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	9		
Units: percent				
median (inter-quartile range (Q1-Q3))	0 (0 to 20.3)	0 (0 to 29.5)		

Statistical analyses

Statistical analysis title	Difference of Coverage of lateral incision by mech
Statistical analysis description: Diffence of the coverage of lateral incision by mechanical discrimination test.	
Comparison groups	Group A v Group B
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.11
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Median difference (final values)
Point estimate	3.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	16.5

Secondary: Blocked area assessed by temperature discrimination test

End point title	Blocked area assessed by temperature discrimination test
End point description:	
End point type	Secondary
End point timeframe: On hour post block.	

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	9		
Units: square centimeter				
arithmetic mean (standard deviation)	418 (± 225)	564 (± 182.7)		

Statistical analyses

Statistical analysis title	Difference of blocked area, by temp discrimination
Statistical analysis description:	
Difference of blocked area assessed by temperature discrimination test.	
Comparison groups	Group A v Group B
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.012
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	146.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	35.7
upper limit	256.9

Secondary: Blocked area assessed by mechanical discrimination test	
End point title	Blocked area assessed by mechanical discrimination test
End point description:	
End point type	Secondary
End point timeframe:	
One hour post block.	

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	9		
Units: square centimeter				
arithmetic mean (standard deviation)	369 (± 211.4)	461 (± 156)		

Statistical analyses

Statistical analysis title	Difference of blocked area, by mech discrimination
Statistical analysis description:	
Difference of blocked area assessed by mechanical discrimination test.	
Comparison groups	Group A v Group B

Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.034
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	92.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.8
upper limit	176.6

Secondary: Post-block MVIC ≤80% of baseline

End point title	Post-block MVIC ≤80% of baseline

End point description:

End point type	Secondary

End point timeframe:

1 hour post block.

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	9		
Units: number	2	2		

Statistical analyses

No statistical analyses for this end point

Secondary: No pain during THS at superior portion of posterior incision

End point title	No pain during THS at superior portion of posterior incision

End point description:

End point type	Secondary

End point timeframe:

One hour post block.

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	9		
Units: number	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: No pain during THS at superior portion of lateral incision

End point title	No pain during THS at superior portion of lateral incision

End point description:

End point type	Secondary

End point timeframe:

One hour post block.

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	9		
Units: number	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: No pain during THS at inferior portion of posterior incision

End point title	No pain during THS at inferior portion of posterior incision

End point description:

End point type	Secondary

End point timeframe:

One hour post block.

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	9		
Units: number	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: No pain during THS at inferior portion of lateral incision

End point title	No pain during THS at inferior portion of lateral incision

End point description:

End point type	Secondary

End point timeframe:

One hour post block.

End point values	Group A	Group B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	9		
Units: number	2	2		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

In the period from admission of the first block until 2 hours after admission of the last block.

Assessment type	Systematic

Dictionary used

Dictionary name	ICH-GCP
Dictionary version	Revision 2

Reporting groups

Reporting group title	Overall adverse events

Reporting group description: -

Serious adverse events	Overall adverse events		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	Overall adverse events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	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: In the 2 hours observation periode for adverse events, none were detected, in this group of healthy volonteers.

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