



Clinical trial results:

Sensory distribution of lateral femoral cutaneous nerve block - a randomised, blinded, paired trial in healthy volunteers

Summary

EudraCT number	2016-002643-41
Trial protocol	DK
Global end of trial date	19 December 2016

Results information

Result version number	v1 (current)
This version publication date	13 May 2021
First version publication date	13 May 2021

Trial information

Trial identification

Sponsor protocol code	SM1-KHTY-16
-----------------------	-------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02957903
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Department of Anaesthesiology
Sponsor organisation address	Ringstedgade 61, Næstved, Denmark, 4700
Public contact	office, Department of Anesthesiology, Næstved Hospital, +45 56514002, anaesthesisekretariat@regionsjaelland.dk
Scientific contact	office, Department of Anesthesiology, Næstved Hospital, +45 56514002, anaesthesisekretariat@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	01 March 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 December 2016
Global end of trial reached?	Yes
Global end of trial date	19 December 2016
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

Protection of trial subjects:

The participants were healthy volunteers. Each participant got one block. There were not taken special measurements regarding pain, as, local anesthesia at the point of injection also would create pain.

The surroundings however were kept quite, and participants had privacy.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 November 2016
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:

40 subjects were assessed for eligibility, 19 subjects were excluded due to not meeting inclusion criteria, not eligible for study dates, declined participation.

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	Intervention A
------------------	----------------

Arm description:

Intervention A received a LCFN-block with 8 ml of 0.75% ropivacaine on the right side and a LCFN-block with 8 ml isotonic saline 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 of ropivacaine given perineural at the lateral cutaneous nerve.

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:

Dosage 8 ml of isotonic saline given perineural at the lateral cutaneous nerve.

Arm title	Intervention B
------------------	----------------

Arm description:

Intervention A received a LCFN-block with 8 ml of 0.75% ropivacaine on the left side and a LCFN-block with 8 ml isotonic saline on the right 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 of ropivacaine given perineural at the lateral cutaneous nerve.

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:

Dosage 8 ml of isotonic saline given perineural at the lateral cutaneous nerve.

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

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
Reporting group description:	
Only the 20 enrolled patients are included in the baseline.	

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			
Age in years.			
Units: years			
arithmetic mean	24		
standard deviation	± 3	-	
Gender categorical			
Units: Subjects			
Female	9	9	
Male	11	11	
Height			
Units: cm			
arithmetic mean	178		
standard deviation	± 9	-	
Weight			
Units: kg			
arithmetic mean	73		
standard deviation	± 12	-	
BMI			
Body Mass Index			
Units: kg/squaremeter			
arithmetic mean	23		
standard deviation	± 2	-	
Length of right posterior incision line			
Units: cm			
arithmetic mean	11		
standard deviation	± 2	-	
Length of left posterior incision line			

Units: cm arithmetic mean standard deviation	11 ± 2	-	
Length of right lateral incision line Units: cm arithmetic mean standard deviation	12 ± 2	-	
Length of left lateral incision line Units: cm arithmetic mean standard deviation	13 ± 1	-	
Maximum voluntary isometric contraction right side Units: kg arithmetic mean standard deviation	41 ± 12	-	
Maximum voluntary isometric contraction left side Units: cm arithmetic mean standard deviation	41 ± 13	-	
Heat pain detection threshold right side Units: degree celcius arithmetic mean standard deviation	45 ± 2	-	
Heat pain detection threshold right side Units: degree celcius arithmetic mean standard deviation	45 ± 3	-	
Tonic heat stimulation right side			
Tonic heat stimulation measured with visual analog scale.			
Units: mm arithmetic mean standard deviation	40 ± 20	-	
Tonic heat stimulation left side			
Tonic heat stimulation measured with visual analog scale.			
Units: mm arithmetic mean standard deviation	39 ± 21	-	

End points

End points reporting groups

Reporting group title	Intervention A
-----------------------	----------------

Reporting group description:

Intervention A received a LCFN-block with 8 ml of 0.75% ropivacaine on the right side and a LCFN-block with 8 ml isotonic saline on the left side.

Reporting group title	Intervention B
-----------------------	----------------

Reporting group description:

Intervention A received a LCFN-block with 8 ml of 0.75% ropivacaine on the left side and a LCFN-block with 8 ml isotonic saline on the right side.

Subject analysis set title	Active
----------------------------	--------

Subject analysis set type	Per protocol
---------------------------	--------------

Subject analysis set description:

All subjects for Intervention A and B with their active side.

Subject analysis set title	Placebo
----------------------------	---------

Subject analysis set type	Per protocol
---------------------------	--------------

Subject analysis set description:

All subjectes in intervention group A and B with their placebo side.

Primary: Difference in the percentage coverage of the posterior incision line with temperature discrimination

End point title	Difference in the percentage coverage of the posterior incision line with temperature discrimination
-----------------	--

End point description:

Predefined as the difference in the percentage coverage of the posterior incision line assessed by temperature discrimination test with alcohol soaked gauze,¹¹ between the side given ropivacaine and the side given isotonic saline.

End point type	Primary
----------------	---------

End point timeframe:

1 hour after application of the block

End point values	Active	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: percent				
arithmetic mean (standard deviation)	5.8 (± 17.2)	0.0 (± 0)		

Statistical analyses

Statistical analysis title	Paired students t-test
----------------------------	------------------------

Comparison groups	Placebo v Active
-------------------	------------------

Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.146
Method	Paired students t-test
Parameter estimate	Mean difference (final values)
Point estimate	5.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.2
upper limit	14

Secondary: Difference in the percentage coverage of the lateral incision line with temperature discrimination

End point title	Difference in the percentage coverage of the lateral incision line with temperature discrimination
End point description: Predefined as the difference in the percentage coverage of the lateral incision line assessed by temperature discrimination test with alcohol soaked gauze, 11 between the side given ropivacaine and the side given isotonic saline.	
End point type	Secondary
End point timeframe: 1 hour after block.	

End point values	Active	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: percent				
arithmetic mean (standard deviation)	18.9 (± 26.6)	0.0 (± 0.0)		

Statistical analyses

Statistical analysis title	Paired students t-test
Statistical analysis description: Mean difference between active and placebo side.	
Comparison groups	Placebo v Active
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	Paired students t-test
Parameter estimate	Mean difference (final values)
Point estimate	18.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	6.5
upper limit	31.4

Secondary: Difference in the percentage coverage of the posterior incision line with pinprick

End point title	Difference in the percentage coverage of the posterior incision line with pinprick
End point description:	Coverage of the posterior incision line assessed by pinprick
End point type	Secondary
End point timeframe:	1 hour after block

End point values	Active	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: percent				
arithmetic mean (standard deviation)	4.3 (± 8.7)	0.0 (± 0.0)		

Statistical analyses

Statistical analysis title	Mean difference pinprick posterior incision
Comparison groups	Active v Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.041
Method	Paired students t-test
Parameter estimate	Mean difference (final values)
Point estimate	4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	8.4

Secondary: Difference in the percentage coverage of the lateral incision line with pinprick

End point title	Difference in the percentage coverage of the lateral incision
-----------------	---

line with pinprick

End point description:

Coverage of the posterior incision line assessed by pinprick

End point type	Secondary
----------------	-----------

End point timeframe:

1 hour after block.

End point values	Active	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: percent				
arithmetic mean (standard deviation)	22.7 (\pm 32.3)	0.0 (\pm 0.0)		

Statistical analyses

Statistical analysis title	Mean difference pinprick lateral incision
Comparison groups	Placebo v Active
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	Paired students t-test
Parameter estimate	Mean difference (final values)
Point estimate	22.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.6
upper limit	37.7

Secondary: Heat pain detection threshold posterior line, superior point

End point title	Heat pain detection threshold posterior line, superior point
-----------------	--

End point description:

HPDT, a computer-controlled thermode set to heat by 1°C/s from 32 to 52°C was used to assess the lowest temperature that was perceived as painful. The participants pushed a button, when the heat sensation turned into a sensation of pain.

End point type	Secondary
----------------	-----------

End point timeframe:

1 hour after block

End point values	Active	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: degree celsius				
arithmetic mean (standard deviation)	45.0 (± 2.6)	46.1 (± 2.4)		

Statistical analyses

Statistical analysis title	Mean difference HPDT posterior incision line
Statistical analysis description:	
Superior point	
Comparison groups	Placebo v Active
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.013
Method	Paired students t-test
Parameter estimate	Mean difference (final values)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	1.9

Secondary: Heat pain detection threshold posterior line, inferior point

End point title	Heat pain detection threshold posterior line, inferior point
End point description:	
HPDT, a computer-controlled thermode set to heat by 1°C/s from 32 to 52°C was used to assess the lowest temperature that was perceived as painful. The participants pushed a button, when the heat sensation turned into a sensation of pain.	
End point type	Secondary
End point timeframe:	
1 hour after block.	

End point values	Active	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: degree celsius				
arithmetic mean (standard deviation)	45.5 (± 3.1)	45.2 (± 2.4)		

Statistical analyses

Statistical analysis title	Mean difference HPDT posterior incision line
Statistical analysis description:	
Inferior point	
Comparison groups	Active v Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.619
Method	Paired students t-test
Parameter estimate	Mean difference (final values)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	1.9

Secondary: Heat pain detection threshold lateral line, superior point

End point title	Heat pain detection threshold lateral line, superior point
End point description:	
HPDT, a computer-controlled thermode set to heat by 1°C/s from 32 to 52°C was used to assess the lowest temperature that was perceived as painful. The participants pushed a button, when the heat sensation turned into a sensation of pain.	
End point type	Secondary
End point timeframe:	
1 hour after block.	

End point values	Active	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: degree celsius				
arithmetic mean (standard deviation)	44.8 (± 2.3)	44.7 (± 3.1)		

Statistical analyses

Statistical analysis title	Mean difference HPDT lateral incision line
Statistical analysis description:	
Superior point	
Comparison groups	Placebo v Active

Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.823
Method	Paired students t-test
Parameter estimate	Mean difference (final values)
Point estimate	0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	0.9

Secondary: Heat pain detection threshold lateral line, inferior point

End point title	Heat pain detection threshold lateral line, inferior point
End point description:	
HPDT, a computer-controlled thermode set to heat by 1°C/s from 32 to 52°C was used to assess the lowest temperature that was perceived as painful. The participants pushed a button, when the heat sensation turned into a sensation of pain.	
End point type	Secondary
End point timeframe:	
1 hour after block.	

End point values	Active	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: degree celsius				
arithmetic mean (standard deviation)	46.0 (± 3.8)	45.3 (± 2.3)		

Statistical analyses

Statistical analysis title	Mean difference HPDT lateral incision line
Statistical analysis description:	
Inferior point	
Comparison groups	Active v Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.387
Method	Paired students t-test
Parameter estimate	Mean difference (final values)
Point estimate	0.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	2.2

Secondary: Tonic heat stimulation posterior line, superior point

End point title	Tonic heat stimulation posterior line, superior point
-----------------	---

End point description:

When testing pain during heat stimulation, the thermode heated to 45°C for 30 s and pain was assessed by the subject using Visual Analogue Score (VAS) from 0 to 100 mm (0 mm being no pain, 100 mm being worst pain imaginable).

End point type	Secondary
----------------	-----------

End point timeframe:

1 hour after block.

End point values	Active	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: mm				
arithmetic mean (standard deviation)	30.3 (± 18.8)	33.0 (± 20.8)		

Statistical analyses

Statistical analysis title	Mean difference Tonic Heat posterior incision line
----------------------------	--

Statistical analysis description:

Superior point

Comparison groups	Active v Placebo
-------------------	------------------

Number of subjects included in analysis	40
---	----

Analysis specification	Pre-specified
------------------------	---------------

Analysis type	superiority
---------------	-------------

P-value	= 0.048
---------	---------

Method	Paired students t-test
--------	------------------------

Parameter estimate	Mean difference (final values)
--------------------	--------------------------------

Point estimate	6.2
----------------	-----

Confidence interval

level	95 %
-------	------

sides	2-sided
-------	---------

lower limit	0.05
-------------	------

upper limit	12.3
-------------	------

Secondary: Tonic heat stimulation posterior line, inferior point

End point title	Tonic heat stimulation posterior line, inferior point
-----------------	---

End point description:

When testing pain during heat stimulation, the thermode heated to 45°C for 30 s and pain was assessed by the subject using Visual Analogue Score (VAS) from 0 to 100 mm (0 mm being no pain, 100 mm being worst pain imaginable).

End point type	Secondary
----------------	-----------

End point timeframe:

1 hour after block.

End point values	Active	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: mm				
arithmetic mean (standard deviation)	30.8 (\pm 23.1)	37.0 (\pm 21.8)		

Statistical analyses

Statistical analysis title	Mean difference Tonic Heat posterior incision line
----------------------------	--

Statistical analysis description:

Inferior point

Comparison groups	Active v Placebo
-------------------	------------------

Number of subjects included in analysis	40
---	----

Analysis specification	Pre-specified
------------------------	---------------

Analysis type	superiority
---------------	-------------

P-value	= 0.048
---------	---------

Method	Paired students t-test
--------	------------------------

Parameter estimate	Mean difference (final values)
--------------------	--------------------------------

Point estimate	6.2
----------------	-----

Confidence interval

level	95 %
-------	------

sides	2-sided
-------	---------

lower limit	0.05
-------------	------

upper limit	12.3
-------------	------

Secondary: Tonic heat stimulation lateral line, superior point

End point title	Tonic heat stimulation lateral line, superior point
-----------------	---

End point description:

When testing pain during heat stimulation, the thermode heated to 45°C for 30 s and pain was assessed by the subject using Visual Analogue Score (VAS) from 0 to 100 mm (0 mm being no pain, 100 mm being worst pain imaginable).

End point type	Secondary
----------------	-----------

End point timeframe:

1 hour after block.

End point values	Active	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: mm				
arithmetic mean (standard deviation)	32.2 (\pm 19.6)	36.7 (\pm 19.9)		

Statistical analyses

Statistical analysis title	Mean difference Tonic Heat lateral incision line
Statistical analysis description:	
Superior point	
Comparison groups	Placebo v Active
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006
Method	Paired students t-test
Parameter estimate	Mean difference (final values)
Point estimate	4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.4
upper limit	7.6

Secondary: Tonic heat stimulation lateral line, inferior point

End point title	Tonic heat stimulation lateral line, inferior point
End point description:	
When testing pain during heat stimulation, the thermode heated to 45°C for 30 s and pain was assessed by the subject using Visual Analogue Score (VAS) from 0 to 100 mm (0 mm being no pain, 100 mm being worst pain imaginable).	
End point type	Secondary
End point timeframe:	
1 hour after block.	

End point values	Active	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: mm				
arithmetic mean (standard deviation)	23.8 (\pm 20.0)	37.3 (\pm 20.5)		

Statistical analyses

Statistical analysis title	Mean difference Tonic Heat lateral incision line
Statistical analysis description:	
Inferior point	
Comparison groups	Active v Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.00018
Method	Paired students t-test
Parameter estimate	Mean difference (final values)
Point estimate	13.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.4
upper limit	19.7

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	Non-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	0		

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: No adverse events are observed in the investigation period.

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.

None reported

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/29468642>