Clinical trial results:
Effect and safety of the iliopsoas plane block in healthy volunteers

Summary

EudraCT number	2018-000089-12
Trial protocol	DK
Global end of trial date	10 June 2018

Results information

Result version number	v1 (current)
This version publication date	18 November 2019
First version publication date	18 November 2019

Trial information

Trial identification

Sponsor protocol code	HIP/FUSION#4

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Department of Clinical Medicine, Aarhus University
Sponsor organisation address	Palle Juul-Jensens Boulevard 165, Aarhus N, Denmark, 8200
Public contact	Niels Dalsgaard Nielsen, Center for Planlagt Kirurgi, Regionshospitalet Silkeborg, +45 22838334, nielsdn@dadlnet.dk
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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	14 June 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 June 2018
Global end of trial reached?	Yes
Global end of trial date	10 June 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate, whether the iliopsoas plane block affects the muscle strength of the quadriceps femoris muscle.

Protection of trial subjects:

No specific measures was used.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 April 2018
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: 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:

We recruited healthy volunteers ≥ 18 years with an American Society of Anesthesiologists physical status classification score (ASA) I-II from a Danish website dedicated to recruit volunteers for research.

Pre-assignment

Screening details:

31 subjects were assessed for eligibility. 9 were excluded (6 meeting exclusion criteria; 3 withdrawing consent).

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, Data analyst, Assessor

Arms

Arm title	Overall trial

Arm description:

Active nerve block, left side

Arm type	Split body, both experimental and placebo
Investigational medicinal product name	Lidocaine-epinephrine with gadoteric acid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Perineural use

Dosage and administration details:

5 mL of lidocaine-epinephrine 18 mg/mL + 5 µg/mL mixed with gadoteric acid 1,75 mg/mL

Number of subjects in period 1	Overall trial
Started	20
Completed	20

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			
Adults (18-64 years)	20	20	
Gender categorical Units: Subjects			
Female	9	9	
Male	11	11	

End points

End points reporting groups

Reporting group title	Overall trial
Reporting group description: Active nerve block, left side	
Subject analysis set title	Baseline
Subject analysis set type	Per protocol
Subject analysis set description: For comparison of baseline values with values obtained 1 hours after nerve block performance (post block).	
Subject analysis set title	Block
Subject analysis set type	Per protocol
Subject analysis set description: Comparison of side with active nerve block vs. side with sham (placebo) nerve block.	
Subject analysis set title	Post block
Subject analysis set type	Per protocol
Subject analysis set description: For comparison of baseline values with values obtained 1 hours after nerve block performance (post block).	
Subject analysis set title	Sham
Subject analysis set type	Per protocol
Subject analysis set description: Comparison of side with active nerve block vs. side with sham (placebo) nerve block.	

Primary: Reduction of maximal force of knee extension one hour after iliopsoas plane block compared to baseline

End point title	Reduction of maximal force of knee extension one hour after iliopsoas plane block compared to baseline
End point description:	
End point type	Primary
End point timeframe: 1 hour after iliopsoas plane block	

End point values	Overall trial	Baseline	Post block	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	14	14	14	
Units: newton				
number (confidence interval 95%)	-9.7 (-22 to 3.0)	354 (299 to 408)	344 (291 to 397)	

Statistical analyses

Statistical analysis title	Ttest
Comparison groups	Baseline v Post block

Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.12
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Point estimate	-9.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22
upper limit	3
Variability estimate	Standard deviation
Dispersion value	22

Secondary: Reduction of maximal force of hip adduction one hour after iliopsoas plane block compared to baseline

End point title	Reduction of maximal force of hip adduction one hour after iliopsoas plane block compared to baseline

End point description:

End point type	Secondary

End point timeframe:

One hour after iliopsoas plane block compared to baseline

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: newton				
arithmetic mean (confidence interval 95%)	0.75 (-12 to 14)			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximal force of knee extension for active vs. sham block

End point title	Maximal force of knee extension for active vs. sham block

End point description:

End point type	Secondary

End point timeframe:

One hour after iliopsoas plane block for

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: newton				
arithmetic mean (confidence interval 95%)	-8.1 (-18 to 2.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximal force of hip adduction for active vs. sham block

End point title	Maximal force of hip adduction for active vs. sham block

End point description:

End point type	Secondary

End point timeframe:

One hour after iliopsoas plane block

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: newton				
arithmetic mean (confidence interval 95%)	3.3 (-7.4 to 14)			

Statistical analyses

No statistical analyses for this end point

Secondary: Anesthesia for pinprick on the lateral thigh

End point title	Anesthesia for pinprick on the lateral thigh

End point description:

End point type	Secondary

End point timeframe:

One hour after iliopsoas plane block

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: No. of subjects with anaesthesia	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Anesthesia for pinprick on the proximal medial corner of patella

End point title	Anesthesia for pinprick on the proximal medial corner of patella

End point description:

End point type	Secondary

End point timeframe:

One hour after iliopsoas plane block

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: No. of subjects with anaesthesia	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Spread of injectate inside the iliopsoas plane

End point title	Spread of injectate inside the iliopsoas plane

End point description:

End point type	Secondary

End point timeframe:

Immediately after iliopsoas plane block

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Fraction				
number (not applicable)	1.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Spread of injectate between the iliofemoral ligament and the iliopsoas muscle

End point title	Spread of injectate between the iliofemoral ligament and the iliopsoas muscle

End point description:

End point type	Secondary

End point timeframe:

Immediately after iliopsoas plane block

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Fraction				
number (not applicable)	0.33			

Statistical analyses

No statistical analyses for this end point

Secondary: Spread of injectate to the interfacial plane between the pectineus and the external obturator muscle

End point title	Spread of injectate to the interfacial plane between the pectineus and the external obturator muscle

End point description:

End point type	Secondary

End point timeframe:

Immediately after iliopsoas plane block

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Fraction				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Spread of injectate to the superficial surface of the iliopsoas muscle

End point title	Spread of injectate to the superficial surface of the iliopsoas muscle

End point description:

End point type	Secondary

End point timeframe:

Immediately after iliopsoas plane block

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Fraction				
number (not applicable)	0.05			

Statistical analyses

No statistical analyses for this end point

Secondary: Intraarticular spread of injectate in the hip joint

End point title	Intraarticular spread of injectate in the hip joint

End point description:

End point type	Secondary

End point timeframe:

Immediately after iliopsoas plane block

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Fraction				
number (not applicable)	0.05			

Statistical analyses

No statistical analyses for this end point

Secondary: Spread of injectate to the posterior side of the hip joint capsule

End point title	Spread of injectate to the posterior side of the hip joint capsule

End point description:

End point type	Secondary

End point timeframe:

Immediately after ilipsoas plane block

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Fraction				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Spread of injectate to the iliopectineal bursa

End point title	Spread of injectate to the iliopectineal bursa

End point description:

End point type	Secondary

End point timeframe:

Immediately after iliopsoas plane block

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Fraction				
number (not applicable)	0.28			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 1 hour after nerve block performance.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Serious adverse events	Overall trial		
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 trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 20 (15.00%)		
General disorders and administration site conditions			
Pain at site of injection			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Musculoskeletal and connective tissue disorders			
Muscular pain			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		

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