Clinical trial results:
The effect of the popliteal plexus block on postoperative pain after reconstruction of the anterior cruciate ligament

Summary

EudraCT number	2017-001708-31
Trial protocol	DK
Global end of trial date	04 December 2017

Results information

Result version number	v1 (current)
This version publication date	11 November 2019
First version publication date	11 November 2019

Trial information

Trial identification

Sponsor protocol code	Protokol_PPB_ACL_21042017

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03130049
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Palle-Juul Jensen Boulevard, Aarhus N, Denmark, 8200
Public contact	Sponsor Thomas Fichtner Bendtsen, Aarhus University Hospital Bedøvelse og operation Nord, +45 51542997, tfb@dadlnet.dk
Scientific contact	Sponsor Thomas Fichtner Bendtsen, Aarhus University Hospital Bedøvelse og operation Nord, +45 51542997, tfb@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	05 December 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 December 2017
Global end of trial reached?	Yes
Global end of trial date	04 December 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this pilot study is to investigate the effect of the popliteal plexus block (PPB) as a supplement to femoral triangle block (FTB) after reconstruction of the anterior cruciate ligament.

Protection of trial subjects:

Prior to start, approval was obtained by the Danish Medicines Agency (EudraCT 2017-001708-31), the Central Denmark Region Committees on Health Research Ethics (1-10-72-100-17), the Danish Data Protection Agency (1-16-02-808-17). Registration was done in the Clinical Trials (NCT03130049) database. The trial was monitored by the Good Clinical Practice Unit and trial was conducted according to the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 September 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: 15
Worldwide total number of subjects	15
EEA total number of subjects	15

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)	15
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted between October and December 2017, and a total of 15 patients were enrolled at the Departments of Day Surgery at Aarhus University Hospital and Horsens Regional Hospital, Denmark. Written, informed consent was obtained from all subjects. Inclusion criteria were patients 18 years or older undergoing primary ACLR with Am

Pre-assignment

Screening details:

Patients were screened at Aarhus University and Horsens Regional Hospital.
26 patients were screened in total (10 at Aarhus University Hospital and 16 at Horsens Regional Hospital. 15 patients were enrolled and completed the trial. In and exclusion criteria were assesssed according to the protocol.

Pre-assignment period milestones

Number of subjects started	15
Number of subjects completed	15

Period 1

Period 1 title	Overall period (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

This was an observational pilot study with no randomization and no blinding.

Arms

Are arms mutually exclusive?	Yes
Arm title	Intervention group

Arm description:

The intervention was an active popliteal plexus block. The patients scored their pain on the NRS from 0-10 on arrival at the post-anesthesia care unit (PACU) and every 15 minutes for up to 60 minutes, which was the maximal length of the postoperative observation period. When any reported pain score was NRS 4 or above, the patient received a popliteal plexus block.

Arm type	Experimental
Investigational medicinal product name	Bupivacaine-epinephrine
Investigational medicinal product code	
Other name	Marcaine-adrenaline
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

The patients received a popliteal plexus block with 10 ml marcaine 5 mg/ml with adrenaline 5 microgram/ml.

Arm title	No intervention group

Arm description:

If the patient did not develop pain of 4 or above on the NRS in the postoperative observation period (60 minutes), the patient would not receive the intervention (popliteal plexus block).

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Intervention group	No intervention group
Started	11	4
Completed	11	4

Baseline characteristics

Reporting groups	
Reporting group title	Overall period

Reporting group description: -

Reporting group values	Overall period	Total	
Number of subjects	15	15	
Age categorical Units: Subjects			
Adults (18-64 years)	15	15	
Age continuous Units: years arithmetic mean standard deviation	 28.7 ± 6.2	 -	
Gender categorical Units: Subjects			
Female Male	2 13	2 13	
BMI			
Body mass index			
Units: kilogram(s)/square meter arithmetic mean standard deviation	 27.1 ± 5.4	 -	

End points

End points reporting groups

Reporting group title	Intervention group

Reporting group description:

The intervention was an active popliteal plexus block. The patients scored their pain on the NRS from 0-10 on arrival at the post-anesthesia care unit (PACU) and every 15 minutes for up to 60 minutes, which was the maximal length of the postoperative observation period. When any reported pain score was NRS 4 or above, the patient received a popliteal plexus block.

Reporting group title	No intervention group

Reporting group description:

If the patient did not develop pain of 4 or above on the NRS in the postoperative observation period (60 minutes), the patient would not receive the intervention (popliteal plexus block).

Primary: PPB success

End point title	PPB success[1][2]

End point description:

The success of the popliteal plexus block (PPB) on postoperative pain after anterior cruciate ligament repair (ACLR) defined as the number of patients with NRS > 3 dropping to af NRS of 3 or below after receiving PPB.

End point type	Primary

End point timeframe:

60 minutes observation period after PPB performance.

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: This was a small unblinded, non-randomized observational pilot study. We report the only the median values for the NRS scores 30 and 60 minutes after PPB and have not applied any statistical test for this outcome.
[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint can only be assessed for patients receiving PPB (intervention group)

End point values	Intervention group			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: NRS 0-10				
median (inter-quartile range (Q1-Q3))				
NRS 30 min after PPB	3 (2 to 3)			
NRS 60 min after PPB	2 (0 to 2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pain after ACLR

End point title	Pain after ACLR

End point description:

The number of patients with a femoral triangle block (FTB) who develop significant pain in the observation period (NRS>3). Only patients with NRS > 3 would then received a PPB.

End point type	Secondary

End point timeframe:

60 minutes after arrival at the PACU

End point values	Intervention group	No intervention group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	4		
Units: NRS 0-10				
Patients with NRS > 3	11	0		
Patients with NRS ≤ 3	0	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Effect of PPB on cutaneous sensation

End point title	Effect of PPB on cutaneous sensation[3]

End point description:

Sensation is graded on a 3-point scale: 0 = no sensation; 1 = reduced sensation; 2 = normal sensation

End point type	Secondary

End point timeframe:

60 minutes after PPB placement

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint can only be assessed for patients receiving PPB (intervention group)

End point values	Intervention group			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: 0-2				
No sensation (=0)	2			
Reduced sensation (=1)	2			
Normal sensation (=2)	7			

Statistical analyses

No statistical analyses for this end point

Secondary: The effect of PPB on muscle strength

End point title	The effect of PPB on muscle strength[4]

End point description:

Muscle strength of ankle dorsal and plantar flexion measured with a handheld dynamometer.

End point type	Secondary

End point timeframe:

Baseline and 60 minutes after PPB

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint can only be assessed for patients receiving PPB (intervention group)

End point values	Intervention group			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: Newton				
median (inter-quartile range (Q1-Q3))				
Dorsal flexion: 60 min after PPB	114 (96 to 140)			
Plantar flexion: 60 min after PPB	136 (114 to 176)			
Dorsal flexion: baseline	140 (114 to 202)			
Plantar flexion: baseline	211 (165 to 228)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

End of the observation period (60 minutes after arrival at the PACU for patients not receiving PPB and 60 minutes after PPB placement for patients receiving PPB)

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10.0

Reporting groups

Reporting group title	Intervention group

Reporting group description:

The intervention was an active popliteal plexus block. The patients scored their pain on the NRS from 0-10 on arrival at the post-anesthesia care unit (PACU) and every 15 minutes for up to 60 minutes, which was the maximal length of the postoperative observation period. When any reported pain score was NRS 4 or above, the patient received a popliteal plexus block.

Reporting group title	No intervention group

Reporting group description:

If the patient did not develop pain of 4 or above on the NRS in the postoperative observation period (60 minutes), the patient would not receive the intervention (popliteal plexus block).

Serious adverse events	Intervention group	No intervention group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Intervention group	No intervention group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 11 (0.00%)	0 / 4 (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: The observation period was very short - 60 minutes. The patients were all young and healthy patients (ASA I) undergoing ACL repair and they did not experience any non-serious adverse events in the 60 minutes observation 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.

Observational pilot study - no randomization and blinding

Notes: