



Clinical trial results:

The effect of subpectineal obturator nerve block on opioid consumption and pain after hip arthroscopy

A double-blind randomized, controlled trial

Summary

EudraCT number	2020-001215-24
Trial protocol	DK
Global end of trial date	07 July 2021

Results information

Result version number	v1 (current)
This version publication date	08 September 2024
First version publication date	08 September 2024

Trial information

Trial identification

Sponsor protocol code	7-190320
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Palle Juul-Jensens Boulevard, Aarhus, Denmark, 8200
Public contact	Thomas Fichtner Bendtsen, Aarhus University Hospital, +45 51542997, tfb@dadlnet.dk
Scientific contact	Thomas Fichtner Bendtsen, Aarhus University Hospital, +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	07 July 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 July 2021
Global end of trial reached?	Yes
Global end of trial date	07 July 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of the trial is to assess the analgesic effect of preoperatively placed active or placebo subpectineal obturatorius nerve block for elective primary hip arthroscopy.
The primary objective of the study is to investigate morphine consumption

Protection of trial subjects:

The study was approved by the Central Denmark Region Committee on Health Research Ethics (reference number 1-10-72-82-20) and the Danish Medicines Agency

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2020
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: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	40
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were screened for inclusion at the first ambulatory contact at Horsens Regional Hospital, Horsens, Denmark, and informed oral and written consent was obtained before surgery. Patients eligible for ambulatory hip arthroscopy surgery indicated by femoroacetabular impingement disease were included according to in- and exclusion criterias

Pre-assignment

Screening details:

Patients were screened for inclusion at the first ambulatory contact at Horsens Regional Hospital, Horsens, Denmark, and informed oral and written consent was obtained before surgery. Patients eligible for ambulatory hip arthroscopy surgery indicated by femoroacetabular impingement disease were included according to in- and exclusion criterias

Period 1

Period 1 title	Intervention (overall period)
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	Active SOB

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Bupivacaine 5 mg/ mL+Epinephrine 5 µg/mL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Perineural use

Dosage and administration details:

15 ml Bupivacaine 5 mg/ mL+Epinephrine 5 µg/mL

Arm title	Placebo SOB
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Arm description: -

Arm type	Placebo
Investigational medicinal product name	Saline 9 mg/mL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Perineural use

Dosage and administration details:

15 mL saline 9 mg/ml

Number of subjects in period 1	Active SOB	Placebo SOB
Started	20	20
Completed	0	0
Not completed	20	20
Protocol deviation	20	20

Baseline characteristics

Reporting groups

Reporting group title	Active SOB
Reporting group description: -	
Reporting group title	Placebo SOB
Reporting group description: -	

Reporting group values	Active SOB	Placebo SOB	Total
Number of subjects	20	20	40
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	20	20	40
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical			
Units: Subjects			
Female	11	9	20
Male	9	11	20

End points

End points reporting groups

Reporting group title	Active SOB
Reporting group description: -	
Reporting group title	Placebo SOB
Reporting group description: -	

Primary: IV morphine equivalent consumption

End point title	IV morphine equivalent consumption
End point description:	
End point type	Primary
End point timeframe:	
The first 3 hours in the PACU	

End point values	Active SOB	Placebo SOB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20 ^[1]	20 ^[2]		
Units: milligram(s)				
arithmetic mean (standard deviation)	0 (± 0)	0 (± 0)		

Notes:

[1] - All test subjects excluded due to protocol deviation

[2] - All test subjects excluded due to protocol deviation

Statistical analyses

Statistical analysis title	Unpaired t test
Comparison groups	Active SOB v Placebo SOB
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority ^[3]
P-value	< 0 ^[4]
Method	t-test, 2-sided

Notes:

[3] - All test subjects excluded due to protocol deviation

[4] - All test subjects excluded due to protocol deviation

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

From anesthesia until discharge from the ambulatory surgery department

Assessment type Systematic

Dictionary used

Dictionary name None

Dictionary version 0

Reporting groups

Reporting group title Active SOB group

Reporting group description: -

Reporting group title Placebo SOB group

Reporting group description: -

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

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Active SOB group	Placebo SOB group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	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: There were no adverse events reported in this trial, neither serious nor non-serious. The Good Clinical Practice Unit at Aalborg and Aarhus University Hospitals monitored the trial and confirmed this.

Due to protocol deviation all test subjects were excluded.

No statistics made.

No publication of the study.

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