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	2021-006575-42
Trial protocol	DK
Global end of trial date	31 October 2023

Results information

Result version number	v1 (current)
This version publication date	04 September 2024
First version publication date	04 September 2024

Trial information

Trial identification

Sponsor protocol code	03_14042023

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	27 November 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 October 2023
Global end of trial reached?	Yes
Global end of trial date	31 October 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of the trial is to asses the analgesic effect of preoperatively placed active or placebo subpectineal obturator 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 1-10-72-374-21) and the Danish Medicines Agency

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2022
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:

Active subpectineal obturator nerve block

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/infusion 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

Arm description:

Placebo subpectineal obturator nerve block

Arm type	Placebo
Investigational medicinal product name	Saline 9 mg/mL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection 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	18	16
Not completed	2	4
Lost to follow-up	1	-
Protocol deviation	1	4

Baseline characteristics

Reporting groups	
Reporting group title	Active SOB
Reporting group description:	
Active subpectineal obturator nerve block	
Reporting group title	Placebo SOB
Reporting group description:	
Placebo subpectineal obturator nerve block	

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	16	12	28
Male	4	8	12

End points

End points reporting groups

Reporting group title	Active SOB
Reporting group description: Active subpectineal obturator nerve block	
Reporting group title	Placebo SOB
Reporting group description: Placebo subpectineal obturator nerve block	

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	18	16		
Units: mg				
arithmetic mean (standard deviation)	11.9 (± 5.8)	19.7 (± 6.7)		

Statistical analyses

Statistical analysis title	Unpaired t test
Comparison groups	Active SOB v Placebo SOB
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01
Method	t-test, 2-sided
Parameter estimate	Mean difference (net)

Secondary: Numeric Rating Scale (NRS) pain score

End point title	Numeric Rating Scale (NRS) pain score
End point description:	
End point type	Secondary

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	18	16		
Units: nrs				
median (inter-quartile range (Q1-Q3))	4.5 (3 to 5)	5 (3.5 to 6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adductor strength

End point title	Adductor strength

End point description:

End point type	Secondary

End point timeframe:
Before nerveblock (time 0) and after 3 hours in the PACU

End point values	Active SOB	Placebo SOB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	16		
Units: percent				
arithmetic mean (standard deviation)	80 (± 0.13)	38 (± 0.23)		

Statistical analyses

No statistical analyses for this end point

Secondary: Intraoperative hip traction time

End point title	Intraoperative hip traction time

End point description:

End point type	Secondary

End point timeframe:
Time traction was applied until the termination of hip traction

End point values	Active SOB	Placebo SOB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	16		
Units: minute				
arithmetic mean (standard deviation)	25 (± 7)	22 (± 4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Intraoperative consumption of propofol

End point title	Intraoperative consumption of propofol

End point description:

End point type	Secondary

End point timeframe:

During anesthesia

End point values	Active SOB	Placebo SOB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	16		
Units: milligram(s)				
arithmetic mean (standard deviation)	522 (± 188)	532 (± 122)		

Statistical analyses

No statistical analyses for this end point

Secondary: Intraoperative consumption of Remifentanil

End point title	Intraoperative consumption of Remifentanil

End point description:

End point type	Secondary

End point timeframe:

During anesthesia

End point values	Active SOB	Placebo SOB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	16		
Units: milligram(s)				
arithmetic mean (standard deviation)	2.16 (± 0.68)	2.11 (± 0.64)		

Statistical analyses

No statistical analyses for this end point

Secondary: Length of stay in the PACU

End point title	Length of stay in the PACU

End point description:

End point type	Secondary

End point timeframe:

The time in the PACU

End point values	Active SOB	Placebo SOB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	16		
Units: minute				
arithmetic mean (inter-quartile range (Q1-Q3))	180 (165 to 268)	205 (185 to 223)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of anesthesia

End point title	Duration of anesthesia

End point description:

End point type	Secondary

End point timeframe:

Induction of anesthesia until removal of the laryngeal mask

End point values	Active SOB	Placebo SOB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	16		
Units: minute				
arithmetic mean (standard deviation)	72 (± 13)	69 (± 12)		

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of vomiting

End point title	Frequency of vomiting

End point description:

End point type	Secondary

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	18	16		
Units: number	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Postoperative PONV score

End point title	Postoperative PONV score

End point description:

End point type	Secondary

End point timeframe:

Maximun PONV score 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	18	16		
Units: ponv				
number (not applicable)				
None	18	16		
Mild	0	0		
Moderate	0	0		
Severe	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Patient satisfaction (NRS 0–10)

End point title	Patient satisfaction (NRS 0–10)

End point description:

End point type	Secondary

End point timeframe:

Patient satisfaction (NRS 0–10)

End point values	Active SOB	Placebo SOB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	16		
Units: nrs				
median (inter-quartile range (Q1-Q3))	10 (9 to 10)	9 (8 to 10)		

Statistical analyses

No statistical analyses for this end point

Secondary: Droperidol

End point title	Droperidol

End point description:

End point type	Secondary

End point timeframe:

Droperidol consumption 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	18	16		
Units: milligram(s)				
number (not applicable)				
0 mg	18	16		
0.625 mg	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Ondansetron

End point title	Ondansetron

End point description:

End point type	Secondary

End point timeframe:

Ondansetron consumption 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	18	16		
Units: mg				
number (not applicable)				
0 mg	18	16		
2 mg	0	0		
4 mg	0	0		

Statistical analyses

No statistical analyses for this end point

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 / 18 (0.00%)	0 / 16 (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: 0 %

Non-serious adverse events	Active SOB group	Placebo SOB group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 18 (0.00%)	0 / 16 (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 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.

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/38925710