



## Clinical trial results:

### The effect of iliopsoas plane block on opioid consumption and pain after hip arthroscopy

### A double-blind randomized, controlled trial

#### Summary

EudraCT number	2020-005838-15
Trial protocol	DK
Global end of trial date	04 November 2022

#### Results information

Result version number	v1 (current)
This version publication date	22 August 2024
First version publication date	22 August 2024

#### Trial information

##### Trial identification

Sponsor protocol code	04-22032021
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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	21 November 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 November 2022
Global end of trial reached?	Yes
Global end of trial date	04 November 2022
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 iliopsoas plane block for elective primary hip arthroscopy.

The primary objective of the study is to investigate morphine consumption

Protection of trial subjects:

The trial was approved by the Central Denmark Region Committee on Health Research Ethics (1-10-72-13-21) and the Danish Medicines Agency

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2021
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: 50
Worldwide total number of subjects	50
EEA total number of subjects	50

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)	50
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.

### Period 1

Period 1 title	Intervention (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Data analyst, Carer, Assessor, Subject

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Active IPB

Arm description:

Active iliopsoas plane 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 in pre-filled syringe
Routes of administration	Perineural use

Dosage and administration details:

10 mL: bupivacaine 5 mg/mL + epinephrine 5 µg/mL

<b>Arm title</b>	Placebo IPB
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Arm description:

Placebo iliopsoas plane block

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

Dosage and administration details:

10 mL saline 9 mg/mL

<b>Number of subjects in period 1</b>	Active IPB	Placebo IPB
Started	25	25
Completed	24	25
Not completed	1	0
Physician decision	1	-

## Baseline characteristics

### Reporting groups

Reporting group title	Intervention
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Reporting group description: -

Reporting group values	Intervention	Total	
Number of subjects	50	50	
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)	50	50	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	27	27	
Male	23	23	

## End points

### End points reporting groups

Reporting group title	Active IPB
Reporting group description: Active iliopsoas plane block	
Reporting group title	Placebo IPB
Reporting group description: Placebo iliopsoas plane 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 IPB	Placebo IPB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	25		
Units: mg				
arithmetic mean (standard deviation)	10.4 (± 5.5)	23.8 (± 9.6)		

### Statistical analyses

Statistical analysis title	Mann-Whitney test
Comparison groups	Active IPB v Placebo IPB
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
Variability estimate	Standard deviation

### Secondary: Numeric Rating Scale (NRS) pain score

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

End point type	Secondary
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End point timeframe:

The first 3 hours in the PACU

End point values	Active IPB	Placebo IPB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	25		
Units: NRS				
geometric mean (inter-quartile range (Q1-Q3))	6 (5 to 7)	7 (5 to 8)		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Quadriceps strength

End point title	Quadriceps strength
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End point description:

Quadriceps strength difference (ratio). A proportion where the numerator was preoperative strength minus postoperative strength and the denominator was preoperative strength

End point type	Secondary
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End point timeframe:

Before the nerve block (time 0) and after 3 hours in the PACU

End point values	Active IPB	Placebo IPB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	24		
Units: ratio				
arithmetic mean (standard deviation)	-0.427 ( $\pm$ 0.28)	-0.356 ( $\pm$ 0.29)		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Intraoperative hip traction time

End point title	Intraoperative hip traction time
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End point description:

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

End point values	Active IPB	Placebo IPB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	25		
Units: min				
arithmetic mean (standard deviation)	23 ( $\pm$ 6)	22 ( $\pm$ 6)		

### 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 IPB	Placebo IPB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	25		
Units: minute				
arithmetic mean (standard deviation)	68 ( $\pm$ 12)	67 ( $\pm$ 10)		

### 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:	
From start til end of the anesthesia	



End point values	Active IPB	Placebo IPB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	25		
Units: millicurie(s)/milligram				
arithmetic mean (standard deviation)	558 (± 149)	531 (± 118)		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Intraoperative consumption of Remifentanyl

End point title	Intraoperative consumption of Remifentanyl
End point description:	
End point type	Secondary
End point timeframe:	
From start til end of the anesthesia	

End point values	Active IPB	Placebo IPB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	25		
Units: millicurie(s)/milligram				
arithmetic mean (standard deviation)	2.15 (± 0.70)	2.01 (± 0.57)		

### 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:	
Time of arrival until the patients were ready for discharge	

End point values	Active IPB	Placebo IPB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	25		
Units: minute				
arithmetic mean (standard deviation)	207 (± 57)	218 (± 76)		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Frequency of vomiting

End point title	Frequency of vomiting
End point description: Number of patients vomiting postoperative in the PACU	
End point type	Secondary
End point timeframe: The first 3 hours in the PACU	

End point values	Active IPB	Placebo IPB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	25		
Units: Number	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 IPB	Placebo IPB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	25		
Units: Number				
arithmetic mean (inter-quartile range (Q1-Q3))	10 (9 to 10)	9 (8 to 10)		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Ondansetron mg

End point title	Ondansetron mg
End point description:	
End point type	Secondary
End point timeframe:	
The first 3 hours in the PACU	

End point values	Active IPB	Placebo IPB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	24		
Units: millicurie(s)/milligram				
number (not applicable)				
0 mg	24	22		
2 mg	0	1		
4 mg	1	1		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Droperidol mg

End point title	Droperidol mg
End point description:	
End point type	Secondary
End point timeframe:	
The first 3 hours in the PACU	

End point values	Active IPB	Placebo IPB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	24		
Units: millicurie(s)/milligram				
number (not applicable)				
0 mg	25	22		
0.625 mg	0	2		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Postoperative PONV score

End point title	Postoperative PONV score
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End point description:

End point type	Secondary
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End point timeframe:

The first 3 hours in the PACU

End point values	Active IPB	Placebo IPB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	24		
Units: number				
number (not applicable)				
None	24	22		
Mild	0	1		
Moderate	1	1		
Severe	0	0		

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

From anesthesia until discharge from the ambulatory surgery department

Assessment type	Systematic
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### Dictionary used

Dictionary name	None
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Dictionary version	0
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### Reporting groups

Reporting group title	Active IPB group
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Reporting group description: -

Reporting group title	Placebo IPB group
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Reporting group description: -

Serious adverse events	Active IPB group	Placebo IPB group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (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 IPB group	Placebo IPB group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (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.

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/38050149>