



Clinical trial results:

Laparoscopically inserted transversus abdominis plane block versus local wound anesthesia in laparoscopic peritoneal endometriosis surgery: a prospective randomized controlled double-blinded LTAP-trial

Summary

EudraCT number	2020-004353-80
Trial protocol	FI
Global end of trial date	20 December 2023

Results information

Result version number	v1 (current)
This version publication date	20 February 2025
First version publication date	20 February 2025

Trial information

Trial identification

Sponsor protocol code	179/2020
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04735770
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Oulu university hospital
Sponsor organisation address	Kajaanintie 50, Oulu, Finland, 90220
Public contact	Department of obstetrics and gynecology, Oulu University hospital, sari.koivurova@fimnet.fi
Scientific contact	Department of obstetrics an gynecology, Oulu University hospital, sari.koivurova@fimnet.fi

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	03 February 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 December 2023
Global end of trial reached?	Yes
Global end of trial date	20 December 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this study is to compare the effect and safety of LTAP (Chirocaine 2,5 mg/ml 40 ml) to local wound analgesia (Chirocaine 5mg/ml 10 ml) treating post-laparoscopic pain measured by postoperative opioid consumption.

Protection of trial subjects:

The trial subjects were endometriosis patients who received surgical treatment for their disease. Their possible pain and distress were treated according to generally accepted postoperative treatment protocols such as pain or antiemetic medication and epidural analgesic if needed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 December 2020
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	Finland: 46
Worldwide total number of subjects	46
EEA total number of subjects	46

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)	46
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment was conducted in a single tertiary hospital starting May 2021 and finishing December 2023.

Pre-assignment

Screening details:

Eligible patients were 18-50 yrs of age, ASA 1-3, diagnosed or suspected with endometriosis with indication to surgery.

Exclusion criteria: sleep apnea, ASA>3, contraindications to opioids or NSAIDs, continuous opioid intake preoperatively.

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

Arms

Are arms mutually exclusive?	Yes
Arm title	LTAP arm

Arm description:

The group of patients who received LTAP-block.

Arm type	Experimental
Investigational medicinal product name	levobupivacain
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Infiltration

Dosage and administration details:

LTAP-arm: Levobupivacain 2,5 mg/ml in total 40 ml was administered via LTAP-route and 10 ml of saline was administered locally.

Local wound analgesia arm: Levobupivacain 5mg/ml was administered locally and 40 ml saline via LTAP-route.

Investigational medicinal product name	levobupivacain
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Infiltration

Dosage and administration details:

LTAP-arm: Levobupivacain 2,5 mg/ml in total 40 ml was administered via LTAP-route and 10 ml of saline was administered locally.

Local wound analgesia arm: Levobupivacain 5mg/ml was administered locally and 40 ml saline via LTAP-route.

Arm title	Local wound analgesia arm
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Arm description:

The group of patients who received local wound analgesia.

Arm type	Active comparator
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Investigational medicinal product name	levobupivacain 5 mg/ml
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Infiltration

Dosage and administration details:

Local wound analgesia arm: Levobupivacain 5mg/ml was administered locally and 40 ml saline via LTAP-route.

Number of subjects in period 1	LTAP arm	Local wound analgesia arm
Started	23	23
Completed	23	23

Baseline characteristics

Reporting groups

Reporting group title	LTAP arm
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Reporting group description:

The group of patients who received LTAP-block.

Reporting group title	Local wound analgesia arm
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Reporting group description:

The group of patients who received local wound analgesia.

Reporting group values	LTAP arm	Local wound analgesia arm	Total
Number of subjects	23	23	46
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	25.9 ± 8.24	27.1 ± 6.38	-
Gender categorical Units: Subjects			
Female	23	23	46
Male	0	0	0
BMI Units: kg/m2 arithmetic mean standard deviation	26.0 ± 5.49	25.8 ± 6.21	-

End points

End points reporting groups

Reporting group title	LTAP arm
Reporting group description: The group of patients who received LTAP-block.	
Reporting group title	Local wound analgesia arm
Reporting group description: The group of patients who received local wound analgesia.	

Primary: Opioid consumption

End point title	Opioid consumption
End point description:	
End point type	
Primary	
End point timeframe:	
Postoperative total opioid consumption from the recovery room until hospital discharge.	

End point values	LTAP arm	Local wound analgesia arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: mg				
arithmetic mean (standard deviation)	31.8 (\pm 25.5)	27.5 (\pm 19.3)		

Statistical analyses

Statistical analysis title	Parametric test
Comparison groups	Local wound analgesia arm v LTAP arm
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 1-sided

Primary: Postoperative pain recovery room

End point title	Postoperative pain recovery room
End point description: Pain NRS was measured on a scale 0-10.	
End point type	Primary

End point timeframe:

Postoperative pain measured at the recovery room.

End point values	LTAP arm	Local wound analgesia arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: numbers	6	7		

Statistical analyses

Statistical analysis title	Student's T-Test
Comparison groups	LTAP arm v Local wound analgesia arm
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided

Primary: postoperative pain at 6 hours

End point title	postoperative pain at 6 hours
End point description:	
End point type	Primary
End point timeframe:	
Postoperative pain a 6 hours on a scale of 0-10.	

End point values	LTAP arm	Local wound analgesia arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: numbers	3	3		

Statistical analyses

Statistical analysis title	student's T-test
Comparison groups	LTAP arm v Local wound analgesia arm

Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided

Primary: Postoperative pain at 12 hours

End point title	Postoperative pain at 12 hours
End point description:	
End point type	Primary
End point timeframe:	
Postoperative pain at 12 hours on a scale of 0-10.	

End point values	LTAP arm	Local wound analgesia arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: numbers	2	3		

Statistical analyses

Statistical analysis title	student's T-test
Comparison groups	LTAP arm v Local wound analgesia arm
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided

Primary: Postoperative pain at 24 hours

End point title	Postoperative pain at 24 hours
End point description:	
End point type	Primary
End point timeframe:	
Postoperative pain at 24 hours on scale of 0-10.	

End point values	LTAP arm	Local wound analgesia arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: numbers	4	3		

Statistical analyses

Statistical analysis title	student's t-test
Comparison groups	LTAP arm v Local wound analgesia arm
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided

Primary: Time to discharge

End point title	Time to discharge
End point description:	
End point type	Primary
End point timeframe:	
Time to discharge from the hospital.	

End point values	LTAP arm	Local wound analgesia arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	23		
Units: hours				
arithmetic mean (standard deviation)	24 (± 4)	28 (± 14)		

Statistical analyses

Statistical analysis title	Student's t-test
Comparison groups	LTAP arm v Local wound analgesia arm
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events due to intervention studied would have been assessed during surgery (at the time of intervention) or during hospitalization. Adverse event due to surgery were assessed within a month after surgery.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.1
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Reporting groups

Reporting group title	LTAP-group
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Reporting group description:

23 subjects receiving LTAP block.

Reporting group title	Local wound analgesia group
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Reporting group description:

23 study subjects receiving local wound analgesia.

Serious adverse events	LTAP-group	Local wound analgesia group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 23 (0.00%)	0 / 23 (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: 2 %

Non-serious adverse events	LTAP-group	Local wound analgesia group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 23 (4.35%)	0 / 23 (0.00%)	
Infections and infestations			
postoperative infection			
subjects affected / exposed	1 / 23 (4.35%)	0 / 23 (0.00%)	
occurrences (all)	1	0	

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.

None.

Notes: