Clinical trial results:
Laparoscopic vs Ultrasound-Guided Transversus Abdominis Plane Block in Minimally Invasive Colon Surgery: A Randomized Controlled Multicentre Clinical Trial

Summary

EudraCT number	2020-001054-22
Trial protocol	DK
Global end of trial date	09 March 2024

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	OPMICS-1

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04311099
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Copenhagen University Hospital - North Zealand
Sponsor organisation address	Dyrehavevej 29, Hillerød, Denmark, 3400
Public contact	Sponsor, Claus Anders Bertelsen, +45 51 90 63 03, cabertelsen@gmail.com
Scientific contact	Sponsor, Claus Anders Bertelsen, +45 51 90 63 03, cabertelsen@gmail.com

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	09 March 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 March 2024
Global end of trial reached?	Yes
Global end of trial date	09 March 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of the trial is to identify the "most simple non-inferior of three different methods", placebo, laparoscopic assisted transverse abdominal plane block (L-TAP) and ultrasound-guided transverse abdominal plane block (US-TAP), using postoperative opioid consumption as a measure of efficacy in patients undergoing elective minimally invasive colon surgery in an ERAS setting. Postoperative pain scores and LOS will also be measured. The simplicity of the three methods is ranked as: 1) placebo, 2) L-TAP and 3) US-TAP.

Protection of trial subjects:

The trial was a pain management study, and all patients received treatment for pain in accordance with hospital guidelines, following generic pain management principles.

Background therapy:

All patients received a bolus injection of Ropivacaine 2 mg/ml 20 ml around the extraction incision in the abdominal wall. Pain management was conducted in accordance with hospital guidelines and the WHO analgesic ladder.

Evidence for comparator:

The trial included two interventions: the laparoscopic-assisted transversus abdominis plane block and the ultrasound-guided transversus abdominis plane block. The ultrasound-guided technique is the more common approach, whereas the laparoscopic-assisted technique is easier and more efficient.
We concluded from the literature review that there was insufficient evidence regarding the effects of the transversus abdominis plane block; therefore, we chose to include a placebo group as a comparator. The trial was conducted step-wise. First, determining the superiority of the transversus abdominis plane block to placebo and then determining the non-inferiority of the laparoscopic-assisted technique to the ultrasound-guided technique.

Actual start date of recruitment	18 January 2021
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: 360
Worldwide total number of subjects	360
EEA total number of subjects	360

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)	103
From 65 to 84 years	240
85 years and over	17

Subject disposition

Recruitment

Recruitment details:

Recruitment was undertaken in five Danish colorectal centres, with the first patient enrolment on January 18, 2021. Enrolment was undertaken in the outpatient clinic by a colorectal surgeon familiar with the trial protocol. Oral and written informed consent were obtained from 360 patients, with the final inclusion date being February 9, 2024.

Pre-assignment

Screening details:

668 patients fulfilled the inclusion criteria and were screened for inclusion. 184 did not meet the exclusion criteria, and 124 declined to participate. Primary reasons for exclusion were a history of open abdominal surgery, concomitant pain condition, language or psychiatric barrier.

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, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

All medications were packaged similarly, and both consistency and colour were similar and indistinguishable by clinicians and patients alike. Data were not unblinded until the analysis for the primary outcome had been conducted.

Arms

Are arms mutually exclusive?	Yes
Arm title	Active laparoscopic block

Arm description:

Received an active laparoscopic-assisted TAP block and a placebo ultrasound-guided TAP block.

Arm type	Active comparator
Investigational medicinal product name	Ropivacain ”Fresenius Kabi” 2 mg/ml
Investigational medicinal product code	45007
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

60ml of Ropivacaine 2mg/ml administered as a peripheral nerve block and local infiltration analgesia.

Arm title	Active ultrasound-guided TAP block

Arm description:

Received an active ultrasound-guided TAP block and a placebo laparoscopic-assisted TAP block.

Arm type	Active comparator
Investigational medicinal product name	Ropivacain ”Fresenius Kabi” 2 mg/ml
Investigational medicinal product code	45007
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

60ml of Ropivacaine 2mg/ml administered as a peripheral nerve block and local infiltration analgesia.

Arm title	Placebo

Arm description:

Received a placebo ultrasound-guided TAP block and a placebo laparoscopic-assisted TAP block.

Arm type	Placebo
Investigational medicinal product name	Natriumklorid "Fresenius Kabi" 9 mg/ml
Investigational medicinal product code	17927
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

80 ml of sodium chloride 9 mg/ml administered as TAP blocks.

Number of subjects in period 1	Active laparoscopic block	Active ultrasound-guided TAP block	Placebo
Started	135	135	90
Completed	127	127	86
Not completed	8	8	4
Protocol deviation	8	8	4

Baseline characteristics

Reporting groups	
Reporting group title	Active laparoscopic block
Reporting group description:	
Received an active laparoscopic-assisted TAP block and a placebo ultrasound-guided TAP block.	
Reporting group title	Active ultrasound-guided TAP block
Reporting group description:	
Received an active ultrasound-guided TAP block and a placebo laparoscopic-assisted TAP block.	
Reporting group title	Placebo
Reporting group description:	
Received a placebo ultrasound-guided TAP block and a placebo laparoscopic-assisted TAP block.	

Reporting group values	Active laparoscopic block	Active ultrasound-guided TAP block	Placebo
Number of subjects	135	135	90
Age categorical Units: Subjects			
Age continuous Units: years median inter-quartile range (Q1-Q3)	 73.8 63.7 to 78.5	 72.7 64.5 to 77.9	 70.5 61.7 to 77.9
Gender categorical Units: Subjects			
Female	50	66	49
Male	85	69	41

Reporting group values	Total		
Number of subjects	360		
Age categorical Units: Subjects			
Age continuous Units: years median inter-quartile range (Q1-Q3)	 -		
Gender categorical Units: Subjects			
Female	165		
Male	195		

End points

End points reporting groups

Reporting group title	Active laparoscopic block
Reporting group description:	
Received an active laparoscopic-assisted TAP block and a placebo ultrasound-guided TAP block.	
Reporting group title	Active ultrasound-guided TAP block
Reporting group description:	
Received an active ultrasound-guided TAP block and a placebo laparoscopic-assisted TAP block.	
Reporting group title	Placebo
Reporting group description:	
Received a placebo ultrasound-guided TAP block and a placebo laparoscopic-assisted TAP block.	

Primary: 24 hour postoperative morphine equivalent consumption (intravenous in milligrams)

End point title	24 hour postoperative morphine equivalent consumption (intravenous in milligrams)
End point description:	
End point type	Primary
End point timeframe:	
24 hour postoperative consumption	

End point values	Active laparoscopic block	Active ultrasound-guided TAP block	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	127	127	86	
Units: milligram(s)/24 hours				
median (inter-quartile range (Q1-Q3))	15.8 (8.3 to 25.2)	19.2 (6.8 to 33.8)	22.0 (13.3 to 33.3)	

Statistical analyses

Statistical analysis title	Absolute difference L-TAP vs placebo
Comparison groups	Active laparoscopic block v Placebo
Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.01
Method	Regression, Linear
Parameter estimate	Mean difference (final values)
Point estimate	-5.9

Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-11.3
upper limit	-0.5

Statistical analysis title	Absolute difference US-TAP vs placebo
Comparison groups	Placebo v Active ultrasound-guided TAP block
Number of subjects included in analysis	213
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.55
Method	Regression, Linear
Parameter estimate	Mean difference (final values)
Point estimate	-1.4
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-6.8
upper limit	4

Statistical analysis title	Absolute difference US-TAP vs L-TAP
Comparison groups	Active ultrasound-guided TAP block v Active laparoscopic block
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	non-inferiority
Method	Regression, Linear
Parameter estimate	Mean difference (final values)
Point estimate	-4.5
Confidence interval	
level	Other: 98.75 %
sides	2-sided
lower limit	-10
upper limit	-1.1

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

18. January 2021 to 9. March 2024.

Assessment type	Systematic

Dictionary used

Dictionary name	ICD-10
Dictionary version	2019

Reporting groups

Reporting group title	Medical and surgical complications to surgery

Reporting group description:

Serious adverse events were registered as this trial was not examining new medications or procedures. No adverse events occurred due to the intervention or intervention medication. All adverse events were due to the surgical procedures for which the participants were admitted.

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: Only serious adverse events were registered for this trial, as described in the trial protocol and approved by the Regional Committee on Health Research Ethics of the Capital Region of Denmark and the Danish Health and Medicines Authority.

Serious adverse events	Medical and surgical complications to surgery		
Total subjects affected by serious adverse events			
subjects affected / exposed	26 / 360 (7.22%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	2		
Surgical and medical procedures			
Postoperative ileus			
subjects affected / exposed	6 / 360 (1.67%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	5 / 360 (1.39%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Postoperative abscess			
subjects affected / exposed	3 / 360 (0.83%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Anastomotic leak			

subjects affected / exposed	4 / 360 (1.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Postoperative wound complication	Additional description: Intraabdominal bleeding af a complication to surgery.		
subjects affected / exposed	4 / 360 (1.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
Respiratory, thoracic and mediastinal disorders			
Pneumonia			
subjects affected / exposed	4 / 360 (1.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0.5 %

Non-serious adverse events	Medical and surgical complications to surgery		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 360 (0.00%)		

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/34851250

http://www.ncbi.nlm.nih.gov/pubmed/39542642

http://www.ncbi.nlm.nih.gov/pubmed/40343534