



Clinical trial results:

Intraoperative clonidine for postoperative pain management in patients undergoing surgical treatment for endometriosis: a prospective, double-blind, randomized controlled trial

Summary

EudraCT number	2022-001810-21
Trial protocol	DK
Global end of trial date	13 August 2024

Results information

Result version number	v1 (current)
This version publication date	28 August 2025
First version publication date	28 August 2025

Trial information

Trial identification

Sponsor protocol code	2022-001810-21
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05560230
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital, Department of Anaesthesiology
Sponsor organisation address	Palle Juul Jensens Boulevard 99, Aarhus N, Denmark, 8200
Public contact	Lone Nikolajsen, Aarhus University Hospital, Department of Anaesthesiology, +45 78464317, lone.nikolajsen@clin.au.dk
Scientific contact	Lone Nikolajsen, Aarhus University Hospital, Department of Anaesthesiology, +45 78464317, lone.nikolajsen@clin.au.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	01 April 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 August 2024
Global end of trial reached?	Yes
Global end of trial date	13 August 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To examine analgesic efficacy and safety of intraoperatively administered intravenous clonidine in patients undergoing surgical treatment for endometriosis on postoperative opioid consumption

Protection of trial subjects:

The study was conducted in accordance with the Declaration of Helsinki and Guidelines for Good Clinical Practice (GCP) and monitored by the GCP unit at Aarhus University Hospital, Aarhus, Denmark. The study protocol was approved by the Danish Protection Agency, Danish Research Ethics Committee, and the Danish Medicine Agency

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 October 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: 120
Worldwide total number of subjects	120
EEA total number of subjects	120

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)	120
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

Patients scheduled for endometriosis surgery will be approached. The anasthetists will go over study information. If patients give preliminary consent to participate, the project staff will contact them and provide them with information about the study. Patients will provide oral and written consent on the day of surgery.

Pre-assignment

Screening details:

The anasthetists will check in- and exclusion criteria during their visit to the clinic.

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	Intervention

Arm description:

The study drug was given as a single intravenous dose (clonidine 150 µg).
100 ml bag including isotonic saline and the study drug (clonidine 150 µg) will be infused over 5-10 minutes.

Arm type	Experimental
Investigational medicinal product name	Clonidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

150 microgram

Arm title	Control
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Arm description:

100 ml bag including isotonic saline and the study drug (isotonic saline) will be infused over 5-10 minutes.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Number of subjects in period 1	Intervention	Control
Started	57	63
Completed	57	63

Baseline characteristics

Reporting groups

Reporting group title	Intervention
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Reporting group description:

The study drug was given as a single intravenous dose (clonidine 150 µg).
100 ml bag including isotonic saline and the study drug (clonidine 150 µg) will be infused over 5-10 minutes.

Reporting group title	Control
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Reporting group description:

100 ml bag including isotonic saline and the study drug (isotonic saline) will be infused over 5-10 minutes.

Reporting group values	Intervention	Control	Total
Number of subjects	57	63	120
Age categorical Units: Subjects			
Adults (18-64 years)	57	63	120
Age continuous Units: years			
arithmetic mean	37	37	
standard deviation	± 7	± 8	-
Gender categorical Units: Subjects			
Female	57	63	120

End points

End points reporting groups

Reporting group title	Intervention
Reporting group description: The study drug was given as a single intravenous dose (clonidine 150 µg). 100 ml bag including isotonic saline and the study drug (clonidine 150 µg) will be infused over 5-10 minutes.	
Reporting group title	Control
Reporting group description: 100 ml bag including isotonic saline and the study drug (isotonic saline) will be infused over 5-10 minutes.	

Primary: Cumulative opioid consumption (IV morphine)

End point title	Cumulative opioid consumption (IV morphine)
End point description:	
End point type	Primary
End point timeframe: within the first three hours after arrival at the post-anesthesia care unit (PACU)	

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	63		
Units: milligram(s)				
median (inter-quartile range (Q1-Q3))	5 (0 to 10)	10 (0 to 16.5)		

Statistical analyses

Statistical analysis title	Mann-Whitney
Comparison groups	Intervention v Control
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.032
Method	Wilcoxon (Mann-Whitney)

Secondary: Cumulative opioid consumption (IV morphine)

End point title	Cumulative opioid consumption (IV morphine)
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End point description:

End point type	Secondary
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End point timeframe:

within the first six hours after arrival at the PACU

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	63		
Units: milligram(s)				
median (inter-quartile range (Q1-Q3))	5 (0 to 14)	11 (3.9 to 17)		

Statistical analyses

Statistical analysis title	Mann-Whitney
Comparison groups	Intervention v Control
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.036
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Within 6 hours after arrival at the PACU

Assessment type	Systematic
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Dictionary used

Dictionary name	none
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Dictionary version	0.0
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Reporting groups

Reporting group title	All patients
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Reporting group description: -

Serious adverse events	All patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 120 (0.83%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	All patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 120 (20.00%)		
Injury, poisoning and procedural complications			
Perforation of the uterus			
subjects affected / exposed	2 / 120 (1.67%)		
occurrences (all)	2		
Perforation of the bladder			
subjects affected / exposed	1 / 120 (0.83%)		
occurrences (all)	1		
Lesion of the intestine			

subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
Eye disorders Blurred vision subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1		
Gastrointestinal disorders Nausea/vomiting subjects affected / exposed occurrences (all)	14 / 120 (11.67%) 14		
Respiratory, thoracic and mediastinal disorders Pneumothorax subjects affected / exposed occurrences (all) Apnea subjects affected / exposed occurrences (all)	2 / 120 (1.67%) 2 1 / 120 (0.83%) 1		
Skin and subcutaneous tissue disorders Itching subjects affected / exposed occurrences (all) Facial swelling subjects affected / exposed occurrences (all)	1 / 120 (0.83%) 1 1 / 120 (0.83%) 1		

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