



Clinical trial results: Individualised perioperative blood pressure and fluid therapy in oesophagectomy - Study protocol for a prospective randomised controlled trial

Summary

EudraCT number	2021-002816-30
Trial protocol	DK
Global end of trial date	06 October 2024

Results information

Result version number	v1 (current)
This version publication date	04 June 2026
First version publication date	04 June 2026

Trial information

Trial identification

Sponsor protocol code	01072021
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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 Blvd. 99, Aarhus, Denmark, 8200
Public contact	Department of Anaesthesiology, Department of Anaesthesiology, Aarhus University Hospital, peter.juhl-olsen@clin.au.dk
Scientific contact	Department of Anaesthesiology, Department of Anaesthesiology, Aarhus University Hospital, peter.juhl-olsen@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	06 October 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 October 2024
Global end of trial reached?	Yes
Global end of trial date	06 October 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Version 2.1

Date: 03.06.22

To investigate the impact of goal directed fluid therapy (GDT) vs. standard fluid/vasoactive therapy in the perioperative phase of oesophagectomy on comprehensive complication index at 30 days

Protection of trial subjects:

Treated in routine care or with protocolised haemodynamic treatment

Background therapy:

Standard surgical and medical care for oesophagectomy at Aarhus University Hospital

Evidence for comparator:

See local guideline (edok.dk)

Actual start date of recruitment	01 November 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: 102
Worldwide total number of subjects	102
EEA total number of subjects	102

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)	47
From 65 to 84 years	53

85 years and over	2
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Subject disposition

Recruitment

Recruitment details:

Recruitment from one center

Pre-assignment

Screening details:

We screened patients scheduled for oesophagectomy at Aarhus University Hospital

Period 1

Period 1 title	Full trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind ^[1]
Roles blinded	Subject, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

Blinding integrity was assessed by having patients and outcome assessors guess study group allocation after the follow-up period

Arms

Are arms mutually exclusive?	Yes
Arm title	eGDT

Arm description:

Protocolised haemodynamic treatment

Arm type	Experimental
Investigational medicinal product name	norepinephrine
Investigational medicinal product code	C01CA03
Other name	
Pharmaceutical forms	Dispersion for injection
Routes of administration	Infusion

Dosage and administration details:

According to study protokol

Arm title	Standard treatment
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Arm description:

Standard haemodynamic treatment

Arm type	Active comparator
Investigational medicinal product name	Norepinephrine
Investigational medicinal product code	C01CA03
Other name	
Pharmaceutical forms	Emulsion for injection
Routes of administration	Infusion

Dosage and administration details:

According to pre specified protokol

Notes:

[1] - The number of roles blinded appears inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.

Justification: This is appropriate for this trial design

Number of subjects in period 1	eGDT	Standard treatment
Started	50	52
Completed	49	51
Not completed	1	1
Consent withdrawn by subject	1	-
Protocol deviation	-	1

Baseline characteristics

Reporting groups

Reporting group title	Full trial
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Reporting group description: -

Reporting group values	Full trial	Total	
Number of subjects	102	102	
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)	47	47	
From 65-84 years	53	53	
85 years and over	2	2	
Age continuous			
Units: years			
arithmetic mean	68		
standard deviation	± 9	-	
Gender categorical			
Units: Subjects			
Female	27	27	
Male	75	75	

Subject analysis sets

Subject analysis set title	Intention-to-treat
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

All patients that underwent the intervention

Reporting group values	Intention-to-treat		
Number of subjects	100		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	47		

From 65-84 years	53		
85 years and over	2		
Age continuous			
Units: years			
arithmetic mean	68		
standard deviation	± 9		
Gender categorical			
Units: Subjects			
Female	25		
Male	75		

End points

End points reporting groups

Reporting group title	eGDT
Reporting group description:	
Protocolised haemodynamic treatment	
Reporting group title	Standard treatment
Reporting group description:	
Standard haemodynamic treatment	
Subject analysis set title	Intention-to-treat
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
All patients that underwent the intervention	

Primary: Comprehensive Complication Index on postoperative day 30

End point title	Comprehensive Complication Index on postoperative day 30
End point description:	
End point type	Primary
End point timeframe:	
postoperative day 30	

End point values	eGDT	Standard treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	51		
Units: 1-100	39	39		

Statistical analyses

Statistical analysis title	Primary Endpoint statistics
Statistical analysis description:	
The between-group differences in CCI 30 days after surgery (primary endpoint) and 90 days after surgery were analysed using linear regression with study group allocation and open/not open procedure as independent variables.	
Comparison groups	eGDT v Standard treatment
Number of subjects included in analysis	100
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.95
Method	Regression, Linear
Parameter estimate	Mean difference (final values)
Point estimate	-0.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.6
upper limit	8.1

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

30 days

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25
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Frequency threshold for reporting non-serious adverse events: 5 %

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: These were reported directly to the Danish Medicines Agency

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.

The sample size was based on an anticipated 35% relative reduction in CCI.
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Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/41452340>

<http://www.ncbi.nlm.nih.gov/pubmed/37125828>