Clinical trial results:
Crystalloid versus colloid for goal directed haemodynamic optimisation in major abdominal cancer surgery.

Summary

EudraCT number	2013-002217-36
Trial protocol	DK
Global end of trial date	30 June 2015

Results information

Result version number	v1 (current)
This version publication date	22 September 2021
First version publication date	22 September 2021
Summary attachment (see zip file)	Original article (Goal_directed_therapy_with_bolus_albumin_5__is_not.9.pdf)

Trial information

Trial identification

Sponsor protocol code	20130021

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Odense University Hospital
Sponsor organisation address	Sdr. Boulevard, Odense, Denmark, 5000
Public contact	Dept. Anaesthesiology V, Odense University Hospital, 0045 65413758, anders.gadegaard.jensen@rsyd.dk
Scientific contact	Dept. Anaesthesiology V, Odense University Hospital, 0045 60630890, j.staehr@rn.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 June 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 June 2015
Global end of trial reached?	Yes
Global end of trial date	30 June 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate differences in intraoperative global and local oxygen delivery in goal directed haemodynamic optimisation with crystalloids versus colloids.

Protection of trial subjects:

This single centre, double blind, randomised controlled trial was approved by The Regional Committees on Health Research Ethics for Southern Denmark (Ref: S-20130021) on 3 March 2014, and was registered at https://eudract.ema.europa.eu/, Identifier: 2013-002217-36. It was conducted at Odense University Hospital, Denmark. The study started 1 May 2014. The trial was conducted in accordance with the Helsinki declaration and guideline for good clinical practice, and monitored by an external agency.

Background therapy:

Anaesthesia and intra-operative monitoring
A standard fasting regime was followed. Standard monitoring included pulse oximetry, three lead electrocardiography, invasive arterial and central blood pressure measurement, and spirometry with inspiratory and expiratory oxygen, carbon dioxide and volatile agent analysis.
In addition, bispectral index score (BIS, monitoring of anaesthesia depth, BISx Power Link, Philips Medical Systems, Eindhoven, The Netherlands) and central temperature were continuously monitored.
General anaesthesia was induced with fentanyl (1 to 3 mg kg1) and propofol (1 to 3mg kg1), and neuromuscular blockade with cisatracurium (0.15mg kg1).
Anaesthesia was maintained with sevoflurane in oxygen enriched air. A thoracic epidural catheter (level Th 6 to 7) was inserted and an infusion of epidural bupivacaine (5mgml1) 3 to 6mlh1 was continued during surgery.
Mechanical ventilation was performed with tidal volumes (Vt) 6 to 8 ml kg1 ideal body weight and positive endexpiratory pressure (PEEP) PEEP 5 to 8mmHg. In thoraco-abdominal oesophageal surgery, the abdominal dissection was performed first, then, following a change to propofol-remifentanil anaesthesia, a double lumen endotracheal tube was inserted. The patient was positioned in the left lateral decubitus jack-knife position and one-lung ventilation of the left lung was established.
All patients were extubated and transferred for postoperative care and observation in an ICU for at least 24 h following the start of surgery until the next morning. The decision to discharge from hospital was at the discretion of the surgeon in charge of the patient.
Systemic and mesenteric flow monitoring
The LiDCOplus (LiDCO Ltd, Cambridge, UK) monitor was attached and calibrated after induction of anaesthesia.

This device uses a transpulmonary lithium indicator dilution technique. Patient-specific calibration from three independentlymeasured COs was obtained. Establishment an

Evidence for comparator:

Studies, comparing colloids with crystalloids in the peri-operative setting have yet to demonstrate a convincing and guideline changing effect.

Actual start date of recruitment	01 April 2014
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: 60
Worldwide total number of subjects	60
EEA total number of subjects	60

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)	20
From 65 to 84 years	40
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were screened for eligibility at the pre-operative anaesthetic consultation and were included on the day of surgery after informed consent.

Pre-assignment

Screening details:

Patients were screened for eligibility at the pre-operative anaesthetic consultation and were included on the day of surgery after informed consent.
A total of 186 patients were screened for eligibility.

Period 1

Period 1 title	Intraoperative (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: -

Arm type	Experimental
Investigational medicinal product name	Human Albumin 5%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

250 ml bolus i.v. PRN.

Arm title	Control

Arm description: -

Arm type	Placebo
Investigational medicinal product name	NaCl 0.9%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for dispersion for infusion
Routes of administration	Intravenous use

Dosage and administration details:

250 mL iv PRN

Number of subjects in period 1	Intervention	Control
Started	30	30
Completed	30	30

Baseline characteristics

Reporting groups	
Reporting group title	Intervention
Reporting group description: -	
Reporting group title	Control
Reporting group description: -	

Reporting group values	Intervention	Control	Total
Number of subjects	30	30	60
Age categorical			
Age (years): HA 68 [62 to 71]. NaCL 65 [59 to 72]			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	10	10	20
From 65-84 years	20	20	40
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	7	11	18
Male	23	19	42

End points

End points reporting groups

Reporting group title	Intervention
Reporting group description: -	
Reporting group title	Control
Reporting group description: -	

Primary: mDO2i

End point title	mDO2i[1]
End point description:	
End point type	Primary
End point timeframe:	
Intraoperative	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Please see published article (PMID Please see peer reviewed publication (attatched, PMID 31972601).

End point values	Intervention	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: ml/min/m2				
median (inter-quartile range (Q1-Q3))	17.0 (7.6 to 27.5)	12.1 (5.8 to 28.7)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 30 days	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	20

Frequency threshold for reporting non-serious adverse events: 0.05 %

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: We had no adverse events.

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