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Optimising blood-circulation and oxygen delivery in planned abdominal aortic surgery

Submission date	Recruitment status	[_] Prospectively registered
03/08/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/09/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/09/2017	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Optimising stroke volume and oxygen delivery in elective abdominal aortic surgery: a randomised controlled trial

Study objectives
Elective abdominal aortic surgery is performed in patients with aneurism or occlusive atherosclerotic disease. These patients often have severe co-morbidity and are at high risk of postoperative complications. Maintaining optimal circulation during aortic surgery is difficult due to aortic cross clamping and often profound haemorrhage in combination with anaesthetising a patient with general atherosclerotic disease.

Precise and individual circulatory therapy can be performed by continuously monitoring and optimising the patient's stroke volume and oxygen delivery during and after surgery. Optimisation is performed by giving colloid boluses to achieve the individual optimal stroke volume intraoperatively, supplemented by infusion of Dobutamine postoperatively to maintain delivery of oxygen above 600 ml min-1 m-2 .

This protocol may reduce postoperative complications and death, as well as length of stay in the Intensive Care Unit and hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Local Medical Ethics Committee (Den Videnskabsetiske Komite for Region Syddanmark) approved in June 2008 (ref: S-20080055)

Study design
Prospective randomised partly blinded controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Elective abdominal aortic surgery; Atherosclerotic abdominal aortic occlusive disease; Abdominal aortic aneurism

Interventions

Patients were assigned to Individual Goal Directed Therapy (IGDT) or control groups by computer-generated random sequence.

The intervention period started preoperatively, when monitoring with the Lithium Dilution Cardiac Output (LiDCO)-plus-system was established and calibrated at arrival to the operating theatre. The intervention period ended 6 hours postoperatively. Patients were followed for 30 days postoperatively.

Establishment and calibration of the LiDCO-plus-system were carried out by a member of the research team who had no involvement in the peri- and postoperative care and decision making. This allowed complete blinding of both surgical, anaesthetic and Post Anaesthetic Care Unit (PACU) clinical teams to LiDCO-plus-system readings in the control group.

All anaesthetic interventions were at the discretion of the anaesthetist responsible for the perioperative management of the patient. All patients received general anaesthesia with fentanyl, thiopental, rocuronium and sevoflurane in oxygen/air. Before induction of anaesthesia an epidural catheter was inserted at the low thoracic level and an epidural infusion of bupivacain with fentanyl was started and continued until postoperative day 2 or 3.

Standard monitoring for both groups included continuous pulse oxymetri, electrocardiography, invasive arterial and central venous blood pressure monitoring, and spirometry with inspiratory and expiratory oxygen, carbondioxide and anaesthetic gas monitoring. Arterial blood gases were analysed at predefined points in both groups.

Stroke volume index (SVI), cardiac index (CI) and oxygen delivery index (DO2I) were continuously monitored, by lithium indicator dilution and pulse power analysis using the LiDCO-plus-system in all patients, but data was blinded in the control group.

All patients were treated to achieve a heart rate < 100 bpm or <20% above baseline, a mean arterial pressure (MAP) between 60-100 mgHg, a central venous pressure (CVP) between 4-16, body temperature > 36,5°C, an arterial oxygen saturation (SaO2) > 94%, a haemoglobin concentration > 6 mmol l-1, and an urine output > 0.5-1.0 ml min-1 kg-1 in the postoperative period.

In all patients crystalloid, colloid, blood products and vasopressors were administered in the peri- and postoperative periods by the anaesthetist based on intra- and postoperative losses, standard haemodynamic parameters and blood-gases.

Intervention: Patients in the IGDT group in the peri- and postoperative period received 250 ml boluses of intravenous colloid solution (Voluven®, Fresenius Kabi AB, Upsala, Sweden) to achieve a sustained rise in SVI of at least 10% for 20 min. Fluid boluses of Voluven® were repeated if SV subsequently decreased or if there was clinical suspicion of hypovolaemia. Furthermore, in the postoperative period, the IGDT group received dobutamine up to a maximum of 10 ug kg-1 min-1 if DO2I did not reach 600 ml min-1 m-2 with intravenous fluid alone. During infusion of dobutamine, monitoring was supplemented with 5-lead-electrocardiography, and at signs of myocardiel ischemia or heart rate > 100 min-1 or > 20% above baseline, infusion was reduced or discontinued.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
One or more severe postoperative complications:
1. Septic shock
2. Pneumonia
3. Superficial wound infection
4. Deep wound infection
5. Abdominal infection
6. Urinary tract infection
7. Pulmonary embolus
8. Acute Respiratory Distress Syndrome (ARDS)
9. Cardiac arrest
10. Acute coronary syndrome
11. Cardiac arrhythmia (acute treatment needed)
12. Pulmonary oedema
13. Deep venous thrombosis
14. Cerebral thrombosis
15. Cerebral haemorrhage
16. Lower limb paresis
17. Acute kidney insufficiency
18. Intraabdominal hypertension
19. Severe upper gastrointestinal bleeding
20. Gastrointestinal paralysis
21. Creatine Kinase (CK) > 5000
22. Reoperation
23. Readmission to ICU
24. Need of respirator
25. Need of hemodialysis
26. Dead

Secondary outcome measures
1. Flow-related haemodynamic parameters (SVI and Do2I) measured by the LiDCO-plus-system (LiDCO Ltd., Cambridge, UK)
2. Length of stay in Intensive Care Unit
3. Length of hospital stay

Overall study start date
01/06/2008

Completion date
01/01/2010

Eligibility

Key inclusion criteria

Consecutive patients admitted for elective abdominal aortic surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
85

Key exclusion criteria
1. Chronic renal end-failure
2. Preoperative Lithium therapy
3. Body weight < 40 Kg (88,18 lbs)

Date of first enrolment
01/06/2008

Date of final enrolment
01/01/2010

Locations

Countries of recruitment
Denmark

Study participating centre
Department of Anaesthesiology and Intensive Care
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Sponsor information

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/037y5zq83

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Lillebaelt Hospital Kolding (Denmark) - Local research fund

Funder Name
The Toyota Fund (Denmark)

Funder Name
Research Initiative of The Danish Society of Anaesthesiology and Intensive Care Medicine (Denmark)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Other publications	01/01/2010	Yes	No
Results article	01/02/2013	Yes	No