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Optimising blood-circulation and oxygen delivery in lower limb arterial surgery

Submission date 06/01/2011	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 24/02/2011	**Overall study status** Completed	
Last Edited 24/02/2011	**Condition category** 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
Haemodynamic optimisation in elective lower limb arterial surgery: a prospective randomised partly blinded controlled trial

Study objectives
Elective lower limb arterial surgery is performed in patients with critical ischaemia due to atherosclerosis. These patients often have severe co-morbidity and are at high risk of post-operative complications. Maintaining optimal circulation is important during and after surgery in patients 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 intra-operatively, supplemented by infusion of dobutamine post-operatively to maintain delivery of oxygen above 600 ml/min/m2.

This protocol may reduce post-operative complications and death, as well as length of stay in the 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-20080056)

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)
Treatment

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
Primary elective lower limb arterial surgery

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

The intervention period started pre-operatively, 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 post-operatively. Patients were followed for 30 days post-operatively.

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 post-operative 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 peri-operative management of the patient. All patients were fasting over night and no pre-operative intravenous fluids were given. Patients received general anaesthesia with fentanyl, thiopental, rocuronium and sevoflurane in oxygen/air or spinal anaesthesia with bupivacain 0.5% spinal solution. In all patients an epidural catheter was inserted at the L3-L4 level and an epidural infusion of bupivacain with fentanyl was initiated before start of surgery or after two hours, if spinal anaesthesia was used 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, carbon dioxide 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 less than 100 bpm or less than 20% above baseline, a mean arterial pressure (MAP) between 60 - 100 mgHg, a central venous pressure (CVP) between 4 - 16, body temperature greater than 36.5°C, an arterial oxygen saturation (SaO2) greater than 94%, a haemoglobin concentration greater than 6 mmol/l, and an urine output greater than 0.5 - 1.0 ml/min/kg in the post-operative period.

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

Intervention:
Patients in the intervention group 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 minutes in the peri- and post-operative period. Fluid boluses of Voluven® were repeated if SV subsequently decreased or if there was clinical suspicion of hypovolaemia. Furthermore, in the post-operative period, the IGDT group received dobutamine up to a maximum of 10 µg/kg /min if DO2I did not reach 600 ml/min/m2 with intravenous fluid alone. During infusion of dobutamine, monitoring was supplemented with 5-lead-electrocardiography, and at signs of myocardial ischaemia or heart rate greater than 100 minutes or greater than 20% above baseline, infusion was reduced or discontinued.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
One or more severe post-operative complications, registered after a 30 days follow up-period:
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) greater than 5000
22. Reoperation
23. Readmission to ICU
24. Need of respiratory support
25. Need of haemodialysis
26. Dead

Secondary outcome measures
1. Flow-related haemodynamic parameters (SVI and Do2I) measured by the LiDCO-plus-system (LiDCO Ltd., Cambridge, UK) at baseline (T0), surgery start (T1), arterial cross-clamping (T2), end of surgery (T3) and every hour 6 hours immediately after surgery (P1 - P6)
2. Length of hospital stay, registered after a 30 days follow up period

Overall study start date
01/06/2008

Completion date
01/10/2010

Eligibility

Key inclusion criteria
1. Patients scheduled for primary elective lower limb arterial surgery
2. Informed consent
3. Aged 46 - 90 years, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. End stage renal failure
2. Lithium therapy
3. Body weight less than 40 kg (88.18 lbs)

Date of first enrolment
01/06/2008

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
Denmark

Study participating centre
Dept. of Anaesthesia and Intensive Care
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

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