ISRCTN50142780 https://doi.org/10.1186/ISRCTN50142780

Central venous oxygen levels (ScvO2) for fluid optimisation in high risk surgical patients

Submission date
26/06/2011

Recruitment status
No longer recruiting

Registration date
24/01/2012

Overall study status
Completed

Last Edited
08/04/2016

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Fluids are routinely given to patients undergoing surgery to make up for fluid losses during the operation. The patient's cardiac output (the amount of blood pumped by the heart) can be monitored to guide fluid treatment, but this requires expensive equipment. In all high-risk patients a thin tube is placed into a large vein in the chest (central venous catheter) for the measurement of blood pressure and for giving drugs. The levels of oxygen and carbon dioxide in the central venous blood can be measured using blood sampled from the central venous catheter. Changes in these levels could be used as markers of changes in cardiac output without the need for expensive equipment. In this study we want to investigate whether changes in these two markers can be used to assess changes in cardiac output.

Who can participate?
High-risk patients aged over 50 undergoing major open abdominal surgery.

What does the study involve?
Arterial and central venous catheters are placed for the monitoring of the patients' arterial and central venous blood pressure, respectively. Cardiac output is monitored by connecting the arterial catheter to a monitor. Blood samples for blood gas analysis are drawn from the arterial and central venous catheters in any patient being given fluids to increase their cardiac output. Levels of oxygen and carbon dioxide are measured from the blood samples and cardiac output is recorded. Another set of blood samples is taken and cardiac output is measured 5 minutes after the fluids have been given. In each patient we perform up to three measurements of the changes in cardiac output and oxygen and carbon dioxide levels in response to fluid treatment.

What are the possible benefits and risks of participating?
The additional blood being taken for the purpose of this study is 24 ml. This small amount is extremely unlikely to alter blood transfusion requirements as the average blood loss for open abdominal surgery is more than 500 ml.

Where is the study run from?
James Cook University Hospital (UK).

When is the study starting and how long is it expected to run for?
October 2010 to October 2011.

Who is funding the study?
1. James Cook University Hospital Trust (UK)
2. NIHR Comprehensive Local Research Networks Flexibility and Sustainability Funding (UK)

Who is the main contact?
Dr Jost Mullenheim

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
10/H0906/61

Study information

Scientific Title
Can changes in central venous oxygen saturation and central venous - arterial partial pressure of carbon dioxide difference predict changes in stroke volume in high risk surgical patients?

Study objectives
We hypothesise that the trend in central venous oxygen levels (ScvO2) and/or central venous - arterial partial pressure of carbon dioxide (CVA- pCO2) difference in response to fluid challenges can be used to assess changes in stroke volume (SV) and hence cardiac output (CO). This will be investigated in 25 high-risk patients undergoing major surgery in which CO monitoring is deemed necessary

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newcastle & North Tyneside 1 Research Ethics Committee, 05 November 2010, ref: 10/H0906/61
Amendments, 09/12/2010

Study design
Single-centre clinical pilot study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Improving outcomes in high-risk surgical patients

Interventions
1. All patients enrolled in the study will receive standard anaesthetic care: after induction of anaesthesia with a hypnotic drug (propofol or thiopental) all patients will receive a balanced anaesthetic consisting of a volatile anaesthetic which is added to the inspiratory gas, muscle relaxant and opioid. An arterial and central venous catheter will be placed for monitoring of arterial and central venous blood pressure respectively. SV and hence CO will be monitored by connecting the existing arterial catheter to a LiDCO® monitor. Haemoglobin will be maintained > 8g/dl, SaO2 ≥94 %, heart rate < 100 bpm, mean arterial blood pressure 60-100 mmHg and temperature at 36-37° C. The ventilator will be set to achieve a pCO2 of 4.5-5.5 kPa. Postoperative analgesia will be provided via epidural or patient controlled analgesia. Similar to other intraoperative fluid optimisation studies SV and hence CO optimisation will be performed after induction of anaesthesia and placement of catheters.

To answer the proposed research question blood samples for blood gas analysis will be drawn simultaneously from the arterial and central venous catheter (2 ml each) in any patient in whom administration of a fluid bolus to increase SV and hence CO is planned. Three consecutive measurements of ScvO2, central venous and arterial pCO2 will be performed from the same blood sample and the average will be calculated and used for further statistical analysis. Immediately after any series of blood samples SV and hence CO will be recorded. Each fluid bolus will contain of 250 ml colloid (Gelofusin® or Volulyte®) i.v. given over 2 minutes. Another set of blood samples will be taken and SV and hence CO will be measured 5 minutes after the fluid bolus has been given. In each patient we will perform up to three consecutive serial measurements of SV and hence CO in response to a fluid bolus and, concurrently, the two surrogate variables SvcO2 and CVA-pCO2-diff. Thus, in each study participant we will take up to 12 blood gas samples (one arterial and one central venous sample before and after a fluid bolus, maximum of three serial measurements in response to three consecutive fluid boluses). Thus, the maximum of additional blood being taken for study purpose is 24 ml. This small amount is extremely unlikely to alter transfusion requirements as average blood loss for open abdominal surgery is more than 500 ml

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

The correlation between changes of stroke volume and hence cardiac output with changes in central venous saturation and central venous arterial partial pressure of carbon dioxide difference, respectively

Key secondary outcome(s))
Sensitivity and specificity of pulse pressure and stroke volume variation and pleth variability index (PVI) to predict an increase of cardiac output by at least 10%

Completion date
01/10/2011

Eligibility

Key inclusion criteria
1. Elective major open abdominal surgery (gastrointestinal, urological, gynaecological or vascular procedures with an expected duration of at least 90 minutes)
2. Requirement for invasive haemodynamic monitoring including arterial and central venous blood pressure and CO measurement
3. More than 50 years of age and at least one of the following:
3.1. Renal impairment (serum creatinine > 130 µmol/l)
3.2. Diabetes mellitus
3.3. Aged 65 years and over
3.4. Presence of a risk factor for cardiac or respiratory disease:
3.4.1. Exercise tolerance ≤ 6 metabolic equivalents (METs)
3.4.2. Anaerobic threshold ≤ 14 ml/kg/min
3.4.3. Past medical history of ischaemic heart disease
3.4.4. Heart failure
3.4.5. Moderate or severe valvular disease
3.4.6. Chronic obstructive pulmonary disease (COPD)
3.4.7. Radiographically confirmed chronic lung disease (COPD, fibrosis)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. No consent
2. Pregnancy
3. Emergency surgery

4. Vascular surgery involving aortic cross clamping
5. Allergy to Gelofusin® and Volulyte®
6. Laparoscopic surgery

Date of first enrolment
01/10/2010

Date of final enrolment
01/10/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
James Cook University Hospital
Middlesbrough
United Kingdom
NE6 5SE

Sponsor information

Organisation
James Cook University Hospital (UK)

ROR
https://ror.org/02vqh3346

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
James Cook University Hospital Trust (UK)

Funder Name

NIHR Comprehensive Local Research Networks Flexibility and Sustainability Funding (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration