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The use of the LiDCORapid monitor to help guide how much fluids to give patients undergoing major head and neck cancer surgery

Submission date 11/11/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/03/2011	**Overall study status** Completed	
Last Edited 10/05/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
8

Study information

Scientific Title
The use of LiDCORapid for fluid optimisation in patients undergoing major head and neck cancer surgery: a randomised controlled pilot study

Acronym
LiDCORapid

Study objectives
Does the use of LiDCORapid intra-operative optimisation influence the time to declaration of medically fit for discharge from hospital following major head and neck cancer surgery?

The null hypothesis is that fluid optimisation using LiDCORapid has no influence on outcomes after major head and neck cancer surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds (Central) Research Ethics Committee, 02/08/2010, ref: 10/H1313/4

Study design
Randomised controlled pilot study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Head and neck cancer

Interventions
Control group:
Patients allocated to traditional fluid management. Tidal ventilation will be set at 8 ml/kg. Maintenance crystalloid will be administered as compound sodium lactate (Hartmanns) at a rate of 1.5 ml/kg/hr. Fluid boli (initially volulyte 6% upto 50 m/kg then a gelatin based colloid thereafter and blood products where indicated) will be administered according to standard management whereby fluid is given guided by a combination of core-peripheral temperature difference and a urine output (aiming to achieve greater than 0.5 ml/kg/hr. Other factors that influence fluid administration will be determined by a combination of heart rate, blood pressure, central venous pressure (CVP), urine output, estimated evaporative fluid loss/blood loss and serial haemoglobin measurements. As a measure of end organ perfusion we will aim to achieve a minimum urine output of 0.5 ml/kg/hour. The LiDCORapid monitor will be obscured from the surgeons view behind the anaesthetic machine and will face away from the surgical team. The screen of the LiDCORapid monitor will be covered.

During control cases the anaesthetic team will intermittently go to the monitor but will not raise the cover (therefore the anaesthetist will remain blinded to the information provided by the LiDCORapid machine). An independent research nurse will collect the data from the monitor at the end of each case.

LiDCORapid intervention group:
Patients allocated to LiDCORapid guided fluid management. Ventilation will be set at 8 ml/kg. Maintenance crystalloid will be administered as compound sodium lactate (Hartmanns) at a rate of 1.5 ml/kg/hr. Fluid administration by the anaesthetist will be guided by the LiDCORapid monitor. Fluid boli (initially volulyte 6% upto 50 m/kg then a gelatin based colloid thereafter and blood products where indicated) will be administered. A fluid bolus of 3 ml/kg will be given when the SVV exhibits a consistent rise above 10%. During cases using the LiDCORapid monitor the anaesthetic team will behave in the same manner as per the control group regarding viewing the LiDCORapid machine. The surgical team who look after the patient post-operatively will be blinded to the study group to which each patient belongs.

At any point where clinical acumen suggests that fluid is necessary despite conflicting information from the monitor this will be given.

Duration of LiDCORapid guided fluid management:
Approximately 11 hours (during major head and neck surgery). Each participant is expected to be in the study from giving consent to when they are discharged from hospital, a total period of approximately 10 days.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Time to being declared medically fit for discharge (in hours from end of operation)

Key secondary outcome(s))
1. Length of stay in intensive treatment unit (ITU) (total time in ICU including note of readmission if occurs)
2. Total number of days in hospital
3. Readmissions within 30 days of surgery
4. Free tissue transfer complications
5. Return to theatre rate
6. Infective complications and their duration
7. Inpatient mortality

Process outcome measures:
8. Difference in stroke volume and cardiac output between control and intervention groups at the beginning and end of the operation
9. Total volume of fluid given intra-operatively, colloid and crystalloid
10. Blood transfusion requirements (transfusion threshold of less than 8 g/dl unless patient has ischaemic heart disease in which case we would aim to keep Hb 9 - 11 g/dl per usual clinical practice

Completion date
31/08/2012

Eligibility

Key inclusion criteria
Any patient (aged over 18 years, either sex) undergoing major head and neck cancer surgery with free tissue transfer reconstruction

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients declining to join the study
2. Patients with an arrhythmia that precludes the use of stroke volume variation (SVV), e.g., atrial fibrillation or significant sinus arrhythmia

Date of first enrolment
01/09/2010

Date of final enrolment
31/08/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Luke's Hospital
Bradford
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Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
Bradford Teaching Hospitals NHS Foundation Trust (UK)

Funder Name
National Institute of Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme application pending as of 11/11/2010

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration