

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 07/03/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 10/05/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/09/2010

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Target sample size is 82 patients (41 in each arm)

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

England

United Kingdom

Study participating centre

St Luke's Hospital

Bradford

United Kingdom

BD5 0NA

Sponsor information

Organisation

Bradford Teaching Hospitals NHS Foundation Trust (UK)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.bradfordresearch.nhs.uk/index.php>

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

Publication and dissemination plan

Not provided at time of registration

1. 2011 conference proceedings in <https://doi.org/10.1016/j.bjoms.2012.04.201>
2. 2012 conference proceedings in <https://doi.org/10.1016/j.bjoms.2012.04.201>

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration