

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 07/03/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 10/05/2018	<b>Condition category</b> 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

Research and Development Department

Bradford Institute for Health Research

Bradford Royal Infirmary

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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