

Study on the benefits of fluid restriction on the recovery from surgery

Submission date 21/08/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/10/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/01/2014	Condition category Cancer	<input type="checkbox"/> Individual participant data

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
SUR011(48-04-07)

Study information

Scientific Title

A randomised, observer-blinded clinical trial of post-operative fluid restriction in elective gastrointestinal surgery

Study objectives

The null hypothesis is that intravenous peri- and post-operative fluid restriction does not affect the rate of complications in the first 30 days following major gastrointestinal surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Norfolk Research Ethics Committee gave approval on the 5th September 2007 (ref: SUR011 [48-04-07])

Study design

Randomised, observer-blinded trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Upper gastrointestinal and colorectal cancer resection

Interventions

A restricted intra- and post-operative fluid regime with the use of ephedrine instead of fluids once losses have been replaced in the event of hypotension as opposed to a standard regime of fluid replacement. All patients will have epidurals for pain relief.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ephedrine

Primary outcome(s)

Grade II complications and above up to 30 days post-surgery.

Key secondary outcome(s)

1. 30 day post-operative mortality
2. Length of hospital stay
3. Post-operative hypotensive episodes. Duration of follow-up: 5 days post-operatively.

Completion date

01/01/2010

Eligibility

Key inclusion criteria

1. All adult patients (both males and females) undergoing elective colorectal or upper gastrointestinal surgery (gastrectomies, oesophagectomies) cancer resection at the Norfolk and Norwich University Hospital NHS Foundation Trust
2. All patients will have epidurals for pain relief

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. American Society of Anaesthesiologists (ASA) classification 4 - 5
2. Chronic renal failure defined as a creatinine greater than 140 $\mu\text{mol/L}$
3. Congestive cardiac failure defined as New York Heart Association (NYHA) class III - IV
4. Pregnancy
5. Diabetes mellitus (excluding diet controlled)
6. Planned post-operative ventilation on intensive treatment unit (ITU)
7. Contraindication to epidural
8. Inability to give informed consent

Date of first enrolment

01/10/2007

Date of final enrolment

01/01/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Norfolk and Norwich University Hospital NHS Foundation Trust

Norwich

United Kingdom

NR4 7UY

Sponsor information

Organisation

Norfolk and Norwich University Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/01wspv808>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-0706-10478)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2013		Yes	No