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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
21/08/2008		☐ Protocol		
Registration date 02/10/2008	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
09/01/2014	Cancer			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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

Drug/device/biological/vaccine name(s)

Ephedrine

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

01/10/2007

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

Age group

Adult

Sex

Both

Target number of participants

234

Key exclusion criteria

- 1. American Society of Anaesthesiologists (ASA) classification 4 5
- 2. Chronic renal failure defined as a creatinine greater than 140 µmol/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

Date of final enrolment

01/01/2010

Locations

Countries of recruitment

England

United Kingdom

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)

Sponsor details

Norfolk and Norwich University Hospital Colney Lane Norwich England United Kingdom NR4 7UY

Sponsor type

Hospital/treatment centre

Website

http://www.nnuh.nhs.uk

ROR

https://ror.org/01wspv808

Funder(s)

Funder type

Funder Name

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

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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