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

Submission date	Recruitment status	[_] Prospectively registered
21/08/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/10/2008	Completed	[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

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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 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
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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes