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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

Contact name
Mr Michael Lewis

Contact details
Norfolk and Norwich University Hospital NHS Foundation Trust
Department of General Surgery
Centre Block
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY
+44 (0)1603 287583
Michael.Lewis@nnuh.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

Not Specified

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

01/10/2007

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

Government

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