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Fluid restriction following open aortic aneurysm surgery

Submission date	Recruitment status	[ ] Prospectively registered
26/01/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/07/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/04/2017	Surgery	[ ] 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
A091805

Study information

Scientific Title
Does peri-operative fluid restriction affect renal function following major abdominal aortic surgery? A single-centre randomised controlled trial

Acronym
PORAS

Study objectives
Fluid restriction following elective open infra-renal abdominal aortic surgery will affect biomarkers of renal impairment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 3 Research Ethics Committee (REC), 08/01/2010, ref: 09/H0306/87

Study design
Single-centre randomised controlled 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Elective infra-renal aortic aneurysm surgery

Interventions
The intervention group will have a fluid-restricted regime of 1.5 l intravenous (IV) fluid per day post-operatively compared to 3 l in the standard regime group. Of course, there is provision for fluid resuscitation in the event that the patient requires this.

The total duration of treatment is 5 days and the follow-up is only inpatient.

Intervention Type
Procedure/Surgery

Phase

Not Applicable

Primary outcome measure
Urinary levels of interleukin-18 (IL-18), neutrophil gelatinase-associate lipocalin (NGAL), retinol binding protein (RBP), albumin/creatinine ratio (ACR), measured at baseline (pre-operative), 6 hours, 12 hours, 24 hours, day 2 ,day 3, day 4, day 5

Secondary outcome measures
All measured as inpatient outcomes:
1. All major complications
2. Major adverse cardiac event (myocardial infarction, unstable angina, arrhythmia)
3. Respiratory complications (including need, duration and extent of ventilatory support)
4. Neurological complications (delirium, stroke)
5. Mortality
6. Length of stay
7. Intensive care unit (ITU)/high dependency unit (HDU) stay
8. Wound dehiscence
9. Gastrointestinal outcome measures:
9.1. Time to passage of first flatus
9.2. Time to passage of first faeces
9.3. Nausea scores
9.4. Time to resumption of normal diet

Overall study start date
01/02/2010

Completion date
01/04/2011

Eligibility

Key inclusion criteria
Elective patients (aged over 18 years, either sex) undergoing open infra-renal abdominal aortic aneurysm (AAA) repair

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Patients undergoing endovascular aortic aneurysm repair
2. Patients undergoing emergency surgery
3. Elective suprarenal AAA repair
4. Severe cardiac failure (New York Heart Association [NYHA] grade IV or myocardial infarction [MI] less than 3 months)
5. Pre-operative serum creatinine greater than 150 mg/dL
6. Pre-operative serum urea greater than 20 mmol/dl
7. Previous history of renal disease
8. Previous renal transplant
9. Patient scheduled to have simultaneous renal procedure at time of surgery
10. Established renal failure requiring renal replacement therapy
11. Previous history of hepatic disease

Date of first enrolment
01/02/2010

Date of final enrolment
01/04/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrookes Hospital
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Research and Development Department
Box 277, Hills Road
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/research/

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
Addenbrooke's Charitable Trust, Cambridge University Hospitals

Alternative Name(s)
Addenbrooke's Charitable Trust, Cambridge University Hospitals NHS Foundation Trust, ACT

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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