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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