

Fluid restriction following open aortic aneurysm surgery

Submission date 26/01/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/07/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/04/2017	Condition category Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ayesha Noorani

Contact details
Cambridge Vascular Unit
Box 201
Addenbrookes Hospital
Cambridge
United Kingdom
CB2 2QQ

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Addenbrookes Hospital

Cambridge

United Kingdom

CB2 2QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration