

# Restrictive versus standard fluid regime in patients undergoing elective infrarenal abdominal aortic aneurysm (AAA) repair

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|--|---|---|
| <b>Submission date</b><br>13/12/2006   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>31/03/2009 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>02/09/2009       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data  |

**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**  
RGHT 00372

# Study information

## Scientific Title

A prospective randomised clinical trial comparing a restrictive with a standard fluid regime in patients undergoing elective infrarenal abdominal aortic aneurysm (AAA) repair

## Study objectives

A restrictive fluid regime for elective open infra-renal abdominal aortic aneurysm (AAA) repair will improve clinical outcomes as judged primarily by a reduction in the number of patients with post-operative complications.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Northern Ireland Ethics Committee gave approval on the 8th November 2006 (ref: 06/NIR02/110)

## Study design

Phase II single centre prospective randomised controlled clinical 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

Abdominal aortic aneurysm

## Interventions

In the standard regimen patients will be given standard fluid volume intra-operatively and post-operatively until day 5, consisting of 3 litres per day. However in the restricted group, less fluid will be given intra-operatively and only 2 litres per day until day 5.

Following discharge patients will be reviewed and examined at a vascular outpatient clinic at the 30-day, 3-month and 12-month post-operative stages.

## Intervention Type

Other

## **Phase**

Phase II

## **Primary outcome measure**

The difference in the number of patients with post-operative complications between the restrictive and standard treated groups.

## **Secondary outcome measures**

1. Duration of hospital stay - recorded on discharge
2. Re-admission to Intensive Care Unit (ICU)/High Dependency Unit (HDU) and length of ICU/HDU stay - recorded following discharge from ICU
3. Oxygen saturation/fraction of inspired oxygen (FiO<sub>2</sub>):partial pressure of oxygen in arterial blood (PaO<sub>2</sub>) ratio - measured at baseline, and daily until day 5
4. Need for renal replacement therapy/estimated glomerular filtration rate (eGFR) - measured at baseline, and daily until day 5
5. First day of initial passage of flatus or faeces - recorded on occurrence
6. Differences in body weight - measured at baseline, and daily until day 5
7. Number of transfused platelet concentrates (PC)/fresh frozen plasma (FFP)/platelets - measured daily until day 5
8. Haematocrit - measured at baseline, and daily until day 5
9. Urinary albumin/creatinine ratio - measured at baseline, and daily until day 5
10. Sequential Organ Failure Assessment (SOFA) score - measured at baseline, and daily until day 5

## **Overall study start date**

01/01/2007

## **Completion date**

01/11/2008

# **Eligibility**

## **Key inclusion criteria**

Adult patients (aged 18 years and over, either sex) admitted for elective open repair of AAA

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Both

## **Target number of participants**

92 (recruitment ceased at 22 participants)

**Key exclusion criteria**

1. Patients with established renal failure
2. Pre-operative haematological disorder
3. Known allergy to agents specified in the standardised anaesthetic protocol
4. Lack of consent
5. Participation in other trials within 30 days

**Date of first enrolment**

01/01/2007

**Date of final enrolment**

01/11/2008

**Locations****Countries of recruitment**

Northern Ireland

United Kingdom

**Study participating centre**

**Royal Victoria Hospital**

Belfast

United Kingdom

BT12 6BA

**Sponsor information****Organisation**

Royal Victoria Hospital (UK)

**Sponsor details**

Grosvenor Road

Belfast

Northern Ireland

United Kingdom

BT12 6BA

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/03rq50d77>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Ulster Hospital Research Fellowship Committee (UK)

# 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/07/2009   |            | Yes            | No              |