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

Submission date 13/12/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/03/2009	**Overall study status** Completed	
Last Edited 02/09/2009	**Condition category** Circulatory System	

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 (FiO2):partial pressure of oxygen in arterial blood (PaO2) 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
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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?
Results article	results	01/07/2009		Yes	No