

The effect of intravenous fluids on abdominal aortic aneurysm surgery

Submission date 15/12/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 14/02/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/05/2014	Condition category Circulatory System	☐ 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

Study information

Scientific Title
The anti-inflammatory properties of hydroxyethyl starches during abdominal aortic aneurysm surgery

Study objectives

That hydroxyethyl starch with a mean molecular weight of 130 kDa (HES130/0.4) has better splanchnic perfusion and thus reduced inflammatory response compared with hydroxyethyl starch of mean molecular weight of 200 kDa (HES200/0.62).

Ethics approval required

Old ethics approval format

Ethics approval(s)

South Birmingham Ethics Committee, April 2001, ref: 5600

Primary study design

Interventional

Study design

Single-centre unblinded randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Systemic inflammatory response during abdominal aortic aneurysm surgery.

Interventions

Blood volume expansion with either HES130/0.4, HES200/0.62 or gelatine.

This trial was carried out at Selly Oak Hospital, Birmingham, UK.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Hydroxyethyl starch

Primary outcome(s)

The following were assessed pre-operatively, at aortic clamping, reperfusion and then at regular time points after reperfusion (2, 4, 8, 12, 48, 72, 96 and 120 hours):

Systemic inflammatory response:

1. Serum C-Reactive Protein (CRP)
2. White cell activation
3. Adhesion molecule expression
4. Endotoxin release
5. Splanchnic perfusion

Key secondary outcome(s)

The following were assessed pre-operatively, at aortic clamping, reperfusion and then at regular time points after reperfusion (2, 4, 8, 12, 48, 72, 96 and 120 hours):

1. Renal dysfunction:

- 1.1. Urinary markers of renal injury
- 1.2. Serum urea and creatinine
- 2. Pulmonary dysfunction:
 - 2.1. Lung injury score

Completion date

01/10/2002

Eligibility

Key inclusion criteria

All patients undergoing elective infra-renal abdominal aortic aneurysm repair using a transperitoneal route

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

- 1. Patients with a history of allergy to any of the study solutions
- 2. Patients with a creatinine of greater than 177 mmol/L
- 3. Patients with significant iliac occlusive disease

Date of first enrolment

01/04/2001

Date of final enrolment

01/10/2002

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Vascular Surgery
Birmingham
United Kingdom
B29 6JD

Sponsor information

Organisation
Fresenius Kabi (Germany)

ROR
<https://ror.org/01v376g59>

Funder(s)

Funder type
Industry

Funder Name
Fresenius Kabi (Germany)

Results and Publications

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	01/04/2007		Yes	No
Results article	results	01/03/2009		Yes	No