The effect of intravenous fluids on abdominal aortic aneurysm surgery

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|---------------------------------|---|--|--|--|
| 15/12/2007 | | ☐ Protocol | | |
| Registration date 14/02/2008 | Overall study status Completed | Statistical analysis plan | | |
| | | [X] 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

Contact name

Mr Rajiv Vohra

Contact details

Department of Vascular Surgery University Hospital Birmingham NHS Trust Selly Oak Hospital Raddlebarn Road Birmingham United Kingdom B29 6JD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Study design

Single-centre unblinded 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 below to request a patient information sheet

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 measure

The following were assessed pre-operatively, at a ortic 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

Secondary outcome measures

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

Overall study start date

01/04/2001

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

Age group

Not Specified

Sex

Both

Target number of participants

60

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

England

United Kingdom

Study participating centre Department of Vascular Surgery

Birmingham United Kingdom B29 6JD

Sponsor information

Organisation

Fresenius Kabi (Germany)

Sponsor details

Fluid Therapy Division International Business Centre Clinical Research Homburg Germany 61346-BAD

Sponsor type

Industry

Website

http://www.fresenius-kabi.com

ROR

https://ror.org/01v376g59

Funder(s)

Funder type

Industry

Funder Name

Fresenius Kabi (Germany)

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