ISRCTN70166506 https://doi.org/10.1186/ISRCTN70166506

The effect of intravenous fluids on abdominal aortic aneurysm surgery

Submission date	Recruitment status	[_] Prospectively registered
15/12/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/02/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/05/2014	Circulatory System	

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 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

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