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Ascorbic Acid in open Abdominal Aortic Aneurysm repair

Submission date	Recruitment status	[ ] Prospectively registered
16/10/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/11/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/07/2015	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
RGHT000396

Study information

Scientific Title
Non-invasive bed-side measurement of systemic endothelial function in patients undergoing abdominal aortic aneurysm repair: modulation by ascorbic acid

Acronym
AAAAA

Study objectives
In adult patients who undergo elective open abdominal aortic aneurysm (AAA) repair, intra-operative treatment with intravenous ascorbic acid improves endothelial function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committees Northern Ireland (ORECNI), 19/06/2007, ref: 07/NIR02/12

Study design
Phase II single-centre prospective double-blind randomised placebo-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
Abdominal aortic aneurysm

Interventions
Participants will be randomised to either 2 g intravenous ascorbic acid or placebo (0.9% saline) infusion for intra-operative administration. Total duration of treatment is time taken to administer the infusion of the study drug: 20 minutes. All arms are followed up to hospital discharge.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Ascorbic acid

Primary outcome measure
Reduction in endothelial dysfunction as measured by plasma von Willebrand Factor (vWF) at fours hours post-removal of aortic cross clamp.

Secondary outcome measures
1. Systemic endothelial function as assessed by:
1.1. Adhesion molecules - soluble intercellular adhesion molecule-1 (sICAM-1), soluble vascular cell adhesion molecule-1 (sVCAM-1), soluble E-Selectin (sE-Selectin), measured pre-operatively and four hours post-removal aortic crossclamp
1.2. Urinary albumin:creatinine ratio (ACR), measured pre-operatively and four hours post-removal aortic crossclamp
1.3. Non-invasive assessment of endothelial function as determined by Pulse Wave Analysis, measured pre-operatively and four hours post-removal aortic crossclamp
2. Pulmonary endothelial dysfunction as measured by pulmonary dead space fraction, measured at post-intubation and pre-extubation approximately 1 hour post-cross clamp removal
3. Inflammatory response as measured by:
3.1. Highly sensitive C reactive protein (hsCRP), measured pre-operatively and four hours post-removal aortic crossclamp
3.2. Exhaled breath condensate pH, myeloperoxidase, and leukotriene B4, measured at post-intubation and pre-extubation approximately 1 hour post-cross clamp removal
4. Oxidative stress as measured by:
4.1. Serum lipid peroxides, measured pre-operatively and four hours post-removal aortic crossclamp
4.2. Urinary F2 isoprostanes, measured pre-operatively and four hours post-removal aortic crossclamp
4.3. Exhaled breath condensate hydrogen peroxide and 8-isoprostane, measured pre-operatively and four hours post-removal aortic crossclamp

Overall study start date
01/01/2008

Completion date
01/08/2009

Eligibility

Key inclusion criteria
Adult patients (aged 18 years or over, either sex) admitted for elective open repair of abdominal aortic aneurysm in the Royal Victoria Hospital.

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
31

Key exclusion criteria
1. Known history hyperoxaluria or glucose-6-phosphate dehydrogenase deficiency
2. Prior antioxidant therapy
3. Known allergy to ascorbic acid or agents specified in the standardised anaesthetic protocol
4. Lack of consent

Date of first enrolment
01/01/2008

Date of final enrolment
01/08/2009

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Royal Victoria Hospital
Belfast
United Kingdom
BT12 6BA

Sponsor information

Organisation
Belfast Health and Social Care Trust (UK)

Sponsor details
Royal Victoria Hospital
Grosvenor Road
Belfast
Northern Ireland
United Kingdom
BT12 6BA

Sponsor type
Hospital/treatment centre

Website
http://www.qub.ac.uk/

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Research organisation

Funder Name
Vascular Anaesthetic Society Great Britain & Ireland (VASGBI) (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	01/12/2015		Yes	No