# Ascorbic Acid in open Abdominal Aortic Aneurysm repair

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>	
16/10/2008	No longer recruiting	Protocol	
Registration date 12/11/2008	Overall study status Completed	Statistical analysis plan	
		[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

#### Contact name

Dr Danny McAuley

#### Contact details

Regional Intensive Care Unit Royal Victoria Hospital Grosvenor Road Belfast United Kingdom BT12 6BA

# 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, intraoperative 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