

Does prophylactic N acetylcysteine decrease the incidence of contrast nephropathy in patients undergoing endovascular abdominal aortic aneurysm (AAA) repair?

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/02/2008	Condition category Surgery	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0544139644

Study information

Scientific Title

Study objectives

Is peri-operative oral N acetylcysteine nephroprotective in patients undergoing endovascular abdominal aortic aneurysm repair?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Surgery: Abdominal aortic aneurysm (AAA) repair

Interventions

Participation offered to all patients undergoing endovascular abdominal aortic aneurysm repair in the Cambridge Vascular Unit, Addenbrooke's Hospital. Consenting patients will be randomised to receive either intra venous saline hydration (current practice) or intravenous saline hydration and oral N acetyl-cysteine (600 mg twice a day (bd) orally (PO) on the day before the procedure; and 600 mg bd PO on the day of the procedure, one dose before, and one dose after the procedure). Evidence of renal injury will be monitored post-procedure by assay of serum creatinine levels, and also by measuring urinary low molecular weight proteins such as N acetyl beta glucosaminidase (NAG) a subclinical marker of renal injury, and albumin and creatinine.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

16/12/2003

Completion date

15/12/2006

Eligibility**Key inclusion criteria**

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

20

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

16/12/2003

Date of final enrolment

15/12/2006

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre
Cambridge Vascular Unit
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (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	01/10/2006		Yes	No