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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 18/02/2008	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
15/12/2006

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK)

Results and Publications

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