ISRCTN69248640 https://doi.org/10.1186/ISRCTN69248640

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

Submission date
30/09/2004

Registration date
30/09/2004

Last Edited
18/02/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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