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Does prophylactic N-AcetylCysteine decrease incidence of contrast nephropathy in patients undergoing peripheral angiography?

Submission date 30/04/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/08/2007	**Overall study status** Completed	
Last Edited 06/08/2010	**Condition category** Urological and Genital Diseases	

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

Study information

Scientific Title

Acronym
NAC as a Nephroprotective agent in Peripheral Angiography

Study objectives
To investigate the role of N-acetylcysteine as a nephroprotective agent in patients undergoing peripheral angiography.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Cambridge Research Ethics Committee on the 24th November 2006 (ref: 06/QI0108/352).

Study design
Prospective 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
Contrast induced nephropathy

Interventions
Treatment group:
Patients will be given 600 mg twice daily N-acetylcysteine the day before the angiogram, and 600 mg twice on the day of the angiogram with intravenous fluids. Samples of urine and blood will be collected before the angiogram and first, second and third day post angiography.

Control group:
Patients will only get intravenous hydration as per normal protocol and will have samples taken like the treatment arm patients.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
N-acetylcysteine

Primary outcome measure
Primarily we are looking for a reduction in the elevation in Albumin/Creatinine ratio and also of other markers of renal damage in urine (retinol binding protein), using the samples collected before the angiogram and first, second and third day post angiography.

Secondary outcome measures
A reduction in the mortality and morbidity related to renal failure that may result secondary to contrast solution used in angiography; this 30-day mortality morbidity reduction will be measured on follow up in clinic normally four to six weeks post angiography.

Overall study start date
01/05/2007

Completion date
01/05/2008

Eligibility

Key inclusion criteria
Any patient undergoing peripheral angiography in the Cambridge Vascular Unit, Addenbrookes Hospital, Cambridge who consents to participation.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Initially 40 patients in pilot study

Key exclusion criteria
1. Any patient undergoing peripheral angiography in Cambridge Vascular Unit
2. Any patient that does not consent to participation in the study
3. Any patient under the age of 18 years
4. Any patient with established renal failure on renal replacement therapy (dialysis)

Date of first enrolment

01/05/2007

Date of final enrolment
01/05/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Box 201
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Cambridge University Hospital NHS Trust (UK)

Sponsor details
Research & Development Department
Addenbrookes Hospital
Cambridge
England
United Kingdom
CB2 2QQ

Sponsor type
Hospital/treatment centre

Website
http://www.addenbrookes.org.uk/

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type

Government

Funder Name
Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust (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	01/04/2011		Yes	No