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Does N-Acetylcysteine (Parvolex®) prophylaxis reduce the incidence of renal impairment after onpump Coronary Artery Bypass Graft surgery? A prospective randomised controlled trial

Submission date 08/07/2007	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 21/08/2007	**Overall study status** Stopped	
Last Edited 07/02/2012	**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
07/Q1403/17

Study information

Scientific Title

Acronym
N-Acetylcysteine prophylaxis for onpump CABG

Study objectives
Prohylatic use of N-Acetylcysteine will decrease the incidence of renal failure in patients undergoing onpump Coronary Artery Bypass Graft (CABG) surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by South Manchester Research Ethics Committee (UK) on the 18th June 2007 (REC ref 07/Q1403/17).

Study design
Prospective randomised double blind 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
Renal impairment

Interventions
For both groups, there will be no change in routine anaesthetic/surgical or post operative management.

The intervention group will be administered 2 g N-Acetylcysteine on the night before surgery (oral), 2 g at induction of anaesthesia (intravenous [IV]) and 2 g IV on the morning of first post operative day. The control group will receive placebos at the same time as the intervention group.

Patients will be followed up until discharge.

As of 07/02/2012, the trial was stopped in September 2010 due to problems with recruitment and the delay resulted in the trial being out of date.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
N-Acetylcysteine (Parvolex®)

Primary outcome measure
Creatinine clearance and serum creatinine levels on second and fifth post operative day and on discharge.

Secondary outcome measures
Length of Intensive Care Unit (ICU) stay.

Overall study start date
01/08/2007

Completion date
31/07/2008

Reason abandoned (if study stopped)
"Participant recruitment issue"

Eligibility

Key inclusion criteria
1. Patients undergoing elective coronoray artery bypass surgery (onpump) at Wythenshawe Hospital
2. Aged 21 - 80 years

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
224 (112 in each group) (Trial stopped in September 2010)

Key exclusion criteria
1. Urgent or emergency cases
2. History of hypersensitivity to N-Acetylcysteine
3. Patients already taking N-Acetylcysteine
4. Patients with renal failure

Date of first enrolment
01/08/2007

Date of final enrolment
31/07/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Consultant Anaesthetist
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
University Hospital of South Manchester NHS Foundation Trust (UK)

Sponsor details
Department of Research and Development
Wythenshawe Hospital
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Sponsor type
Hospital/treatment centre

Website
http://www.smuht.nwest.nhs.uk/

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
University Hospital of South Manchester 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