

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
Registration date 21/08/2007	Overall study status Stopped	☐ Protocol
Last Edited 07/02/2012	Condition category Urological and Genital Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Donna Greenhalgh

Contact details

Consultant Anaesthetist
Wythenshawe Hospital
South Moore Road
Wythenshawe
Manchester
United Kingdom
M23 9LT
+44 (0)161 291 2525
donna.greenhalgh@btopenworld.com

Additional identifiers

Protocol serial number

07/Q1403/17

Study information

Scientific Title

Acronym

N-Acetylcysteine prophylaxis for onpump CABG

Study objectives

Prophylactic 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).

Primary study design

Interventional

Study design

Prospective randomised double blind controlled trial

Study type(s)

Treatment

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the trial was stopped in September 2010 due to problems with recruitment and the delay resulted in the trial being out of date.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(s)

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

Key secondary outcome(s)

Length of Intensive Care Unit (ICU) stay.

Completion date

31/07/2008

Reason abandoned (if study stopped)

"Participant recruitment issue"

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Consultant Anaesthetist

Manchester

United Kingdom

M23 9LT

Sponsor information

Organisation

University Hospital of South Manchester NHS Foundation Trust (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration