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The use of perioperative n-acetylcysteine to prevent renal dysfunction in high-risk patients undergoing coronary artery bypass graft surgery with cardiopulmonary bypass

Submission date 10/05/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/07/2005	**Overall study status** Completed	
Last Edited 12/11/2007	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Karen Burns

Contact details
375 South Street
London
Canada
N6A 4G5

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
To determine whether perioperative intravenous (IV) N-acetylcysteine preserves renal function in high-risk patients undergoing Coronary Artery Bypass Graft (CABG) surgery with Cardiopulmonary Bypass (CPB) compared with placebo.

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)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Coronary artery bypass graft surgery

Interventions
We randomized patients to receive four (two intraoperative and two postoperative) doses of intravenous N-acetylcysteine 600 mg or placebo over a 24-hour period.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure

The primary outcome was the proportion of patients developing postoperative renal dysfunction, defined by an increase in serum creatinine level greater than 0.5 mg/dL (44 micromol/L) or a 25% increase from baseline within the first 5 postoperative days.

Secondary outcome measures
Secondary outcomes included postoperative interventions and complications, the requirement for renal replacement therapy (RRT), adverse events, hospital mortality, and ICU and hospital length of stay.

Overall study start date
01/10/2003

Completion date
01/09/2004

Eligibility

Key inclusion criteria
Elective or urgent coronary artery bypass graft surgery patients with at least one of: pre-esisting renal dysfunction, age greater than or equal to 70, diabetes mellitus, impaired left ventricular function or undergoing concomitant valve or redo surgery.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
295

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/10/2003

Date of final enrolment
01/09/2004

Locations

Countries of recruitment
Canada

Study participating centre
375 South Street
London
Canada
N6A 4G5

Sponsor information

Organisation
The Physician Services Incorporated Foundation (Canada)

Sponsor details
5160 Yonge Street, Suite 1006
Toronto
Canada
M2N 6L9

Sponsor type
Charity

ROR
https://ror.org/0385yzn06

Funder(s)

Funder type
Charity

Funder Name
The Physician Services Incorporated Foundation (Canada)

Funder Name
The Lawson Health Research Institute Internal Research Fund (Canada)

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	20/07/2005		Yes	No