

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	<input type="checkbox"/> Prospectively registered
Registration date 05/07/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/11/2007	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s)

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.

Completion date

01/09/2004

Eligibility

Key inclusion criteria

Elective or urgent coronary artery bypass graft surgery patients with at least one of: pre-existing 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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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)

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

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