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

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

**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 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?
<u>Results article</u>	Results	20/07/2005		Yes	No