ISRCTN39325111 https://doi.org/10.1186/ISRCTN39325111

Prevention of kidney failure using N-acetylcystein and sodium bicarbonate in patients undergoing aortic aneurysm repair.

Submission date 03/11/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/11/2009	**Overall study status** Completed	
Last Edited 27/11/2009	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CHUM 08.110

Study information

Scientific Title
Impact of N-acetylcystein and sodium bicarbonate administration on the prevention of contrast media-induced nephropathy in endovascular aortic aneurysm repair. A prospective, randomised, placebo-controlled trial.

Acronym
NACASRI

Study objectives
The hypothesis underlying this trial is that perioperative intravenous hydration with sodium bicarbonate with perioperative administration of N-Acetylcystein can reduce the incidence of post operative renal failure by 30%, by reducing the incidence of contrast media-induced nephropathy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Research Ethics Committee of CHUM (Comité d'éthique de la recherche du Centre Hospitalier de l'Université de Montréal [CHUM]), Canada on December 18th 2008 (ref: 08.110)

Study design
Prospective randomised double blind placebo controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Aortic surgery. Renal failure.

Interventions
Patients will be randomly allocated, according to a computer-generated list, to one of two groups:
A. Group NB (N-acetylcystein plus sodium bicarbonate)
B. Group S (N-acetylcystein plus Saline).

1. Fifteen minutes before the induction of general anaesthesia, on the day of the surgery, patients in both groups will receive 150 mg/kg IV N-Acetylcystein diluted in 500 ml of normal saline.
2. N-Acetylcystein 1200 mg PO will be given again at 9:00 PM the evening of the surgery and will be given twice (BID) for the first post operative day. It will then be discontinued.
3. Also, one hour prior to the injection of contrast media, which means at the time of induction of general anesthesia, patients in group NS will receive an infusion of sodium bicarbonates (154 MEq/L sodium bicarbonates diluted in 1L of Dextrose 5% in water) at the rate of 3 ml/kg/h, for one hour. This infusion will be continued in these patients at the rate of 1 ml/kg/h for the entire duration of the surgery, until 6 hours post operatively, after which it will be stopped. Patients in group S will receive, at the same infusion rate, a placebo (normal saline).

Intervention Type
Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)
1. the incidence of post operative renal failure;
2. the incidence of post operative renal failure requiring dialysis in the first 30 days following surgery;

Key secondary outcome(s))
The 30-day mortality of patients who had such a surgery.

Completion date
01/01/2011

Eligibility

Key inclusion criteria
1. Patients between 18 and 85 years old.
2. Patients undergoing an elective endovascular aortic repair surgery.
3. ASA I-IV inclusively (ASA: American Society of Anesthesiologists).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patient refusal.
2. Patients who were exposed to contrast media in the last 14 days.
3. Patients presenting with acute renal failure on the day of surgery, as indicated by an increase of 25% or more in serum creatinine from baseline values.
4. History of kidney transplant.
5. Patients with terminal renal failure, treated with dialysis.

Date of first enrolment
01/01/2009

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
Canada

Study participating centre
3840 rue St-Urbain
Montreal
Canada
H2W1T8

Sponsor information

Organisation
University of Montreal Hospital Centre (Centre hospitalier de l'Université de Montréal [CHUM]) (Canada)

ROR
https://ror.org/0410a8y51

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University of Montreal Hospital Centre (Centre hospitalier de l'Université de Montréal [CHUM]) (Canada) - Dept of Pharmacology

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes