

Renal protection by radical-scavenging with N-acetylcysteine in cardiac surgery patients

Submission date 01/08/2006	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 29/08/2006	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 07/01/2021	Condition category Urological and Genital Diseases	☐ 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

Protocol serial number
DFG ME 1257/3-2

Study information

Scientific Title
Renal protection by radical-scavenging with N-acetylcysteine in cardiac surgery patients

Study objectives

N-acetylcysteine (NAC) protects renal function in cardiac surgery patients subjected to Cardio-Pulmonary Bypass (CPB).

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Institutional Ethics Committee of the Medical Faculty of the University of Cologne approved the study on 15th July 2005 (ref: #03-122).

Primary study design

Interventional

Study design

Randomised, double-blind, placebo-controlled clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Renal dysfunction induced by cardiopulmonary bypass (CPB) during cardiac surgery

Interventions

NAC at 100 mg per kg of body weight into the CPB prime followed by NAC infusion at 20 mg per kg of bodyweight per hour until the end of CPB versus placebo (25 patients for each group).

In addition to the standard blood analyses urine samples will be collected. There will be no other interventions, surgical and postoperative treatment will not differ from routine (non-study) patients.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

N-acetylcysteine

Primary outcome(s)

Postoperative renal function assessed by means of the following variables in plasma and urine:

1. Creatinine concentration (primary variable)
2. Cystatin C concentration (co-primary variable)

Key secondary outcome(s)

1. Urea, retinol-binding protein, albumine, alpha1-microglobulin
2. Quantity of post-surgery diuretic medication, serum creatinine clearance
3. Oxidative stress variable in plasma and urine: 8-isoprostaglandinF2a

Completion date

31/12/2008

Eligibility

Key inclusion criteria

1. Male or female
2. No renal dysfunction requiring hemodialysis/hemofiltration
3. Isolated coronary artery disease
4. Left ventricular ejection fraction more than 40%

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

40

Key exclusion criteria

1. Pregnancy
2. Aged over 18 years

Date of first enrolment

01/01/2007

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Germany

Study participating centre

University of Cologne

Cologne

Germany

50924

Sponsor information

Organisation

German Research Foundation (DFG) (Germany)

ROR

<https://ror.org/018mejw64>

Funder(s)

Funder type

Research organisation

Funder Name

German Research Foundation (DFG)

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	01/08/2005	07/01/2021	Yes	No