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

Submission date	Recruitment status	[X] Prospectively registered
01/08/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/08/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/01/2021	Urological and Genital Diseases	

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).

Study design
Randomised, double-blind, placebo-controlled clinical trial

Primary study design
Interventional

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/hemofitration
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