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N-acetylcysteine as a Preventive Measure for Contrast Induced Nephropathy in Intensive Care Patients with Renal Insufficiency

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 19/10/2007	**Condition category** 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

Study information

Scientific Title

Acronym

NACCINIC-trial

Study objectives
On the assumption that N-acetylcysteine might prevent acute contrast induced nephropathy in critically ill patients, we study the effects of prophylactic intravenous administration of N-acetylcysteine in critically ill patients with renal insufficiency.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Primary study design
Interventional

Study design
Multicentre, randomised, double blind, placebo controlled, parallel group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Renal insufficiency

Interventions
Patients are randomly assigned to receive either N-acetylcysteine before and after administration of the contrast agent (acetylcysteine group) or placebo at the same time points (control group).

N-acetylcysteine or placebo is given intravenously in a double blinded fashion. N-acetylcysteine is given at a dose of 5000 mg on the day before and on the day of administration of the contrast agent, for a total of two days.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
N-acetylcysteine

Primary outcome(s)
1. Rise in plasma creatinine greater than 25% within 48 hours after contrast administration
2. Need for Continuous Venous-Venous Haemofiltration (CVVH) therapy at any moment during stay in ICU
3. Duration of CVVH therapy, if initiated
4. Renal insufficiency (for which ongoing renal replacement therapy) at ICU-discharge

Key secondary outcome(s)

No secondary outcome measures

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. (Chronic or acute) renal insufficiency (not presently on renal replacement therapy) defined as a plasma creatinine greater than 180 µmol/L
2. Planned diagnostic imaging procedure requiring the use of intravenous radiographic contrast agents
3. Admitted to one of the participating intensive care units

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Pregnancy
2. No informed consent

Date of first enrolment
01/01/2006

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Intensive Care
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Center (AMC) (The Netherlands) - Department of Intensive Care

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration