

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	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/10/2007	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

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

Study design

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

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/01/2006

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 $\mu\text{mol/L}$
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

Age group

Not Specified

Sex

Not Specified

Target number of participants

246

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)

Sponsor details

Department of Obstetrics and Gynaecology

Meibergdreef 9

Amsterdam

Netherlands

1105 AZ

Sponsor type

Hospital/treatment centre

Website

<http://www.amc.uva.nl/>

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**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