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

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

## 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
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# 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