Neutrophil Gelatinase-Associated Lipocalin as an early detector of ischemic tubular injury in patients admitted to a general Intensive Care Unit.

Published: 24-07-2007
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Objective: Evaluation of the supposed correlation between increased serum and urine NGAL levels (> 350 ng/ml) and significant increases in serum creatinine levels in adult ICU patients compared to preclinical levels

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational non invasive

Summary

ID

NL-OMON31307

Source
ToetsingOnline

Brief title
NGAL study

Condition

- Renal disorders (excl nephropathies)

Synonym
Acute renal dysfunction, kidney failure

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acute renal dysfunction, Intensive Care, NGAL

Outcome measures

Primary outcome

Main study parameters/endpoints: Urine and serum NGAL levels, serum creatinine,

urine sodium, chloride, osmolality and creatinine levels

Secondary outcome

nvt

Study description

Background summary

Rationale: Renal injury is a common problem in the critically ill patient. The wide range of renal injury spreads from sub clinical minimal changes in creatinine levels to complete failure resulting in kidney replacement therapy. An ischemic or nefrotoxic event usually results in increased serum creatinine levels several days later compared to preclinical/pre-admission creatinine levels. Neutrophil Gelatinase-Associated Lipocalin (NGAL) seems to be an early detector of ischemic tubular damage above the cut off point of 350 ng/ml. However, evidence of correlation of increased creatinine levels, fractional sodium and chloride excretion and NGAL levels in serum and urine in adult ICU patients is limited. This warrants a study assessing this correlation in an adult ICU population.

Study objective

Objective: Evaluation of the supposed correlation between increased serum and urine NGAL levels (> 350 ng/ml) and significant increases in serum creatinine levels in adult ICU patients compared to preclinical levels

Study design

Study design: Observational study.

Study burden and risks

nvt

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All consecutive patients admitted to the general ICU meeting the subgroup criteria with obtained informed or deferred consent would be included. Patients will be recruited from the Erasmus MC University Medical Center Rotterdam.

Exclusion criteria

Patients will be excluded if the treating physician judges that study participation is undesirable for medical, medical-ethical or other reasons. Patients with a history of chronic renal failure and preadmission chronic hemofiltration or Continuous Ambulatory Peritoneal Dialysis (CAPD).
Patients with urothelial malignancies will be excluded.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2007
Enrollment:	700
Type:	Actual

Ethics review

Approved WMO Date:	24-07-2007
Application type:	First submission
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Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL17386.078.07