Contrast Induced Nephropathy Evaluation using Multiple immunoAssays

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON33966

Source
ToetsingOnline

Brief title
CINEMA study

Condition

- Other condition
- Nephropathies

Synonym
contrast induced nephropathy; decrease in kidney function caused by contrast media

Health condition

nefrologische bijwerkingen door contrastmiddel toediening

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: ziekenhuisapotheek;radiologie;klinisch-chemisch laboratorium;Pieter van Foreest Instituut te Alkmaar

Intervention

Keyword: CIN, contrast induced nephropathy, microalbuminuria, microglobulinuria

Outcome measures

Primary outcome

Incidence of contrast induced nephropathy

Secondary outcome

microalbuminuria and microglobulinuria

Study description

Background summary

Iodinated contrast media (ICM) are administered intravenously in a large part of Computer Tomography (CT) scans to enhance differences between normal and pathologic structures. The ICM are diagnostic drugs which can cause nephropathy. The incidence of this contrast induced nephropathy (CIN) in high risk patients reported thus far in scientific papers is up to 50 percent. In the general population the incidence reported is 3 to 4 percent. Contrast induced nephropathy accounts for up to 12 percent of all cases of hospital acquired acute renal failure. Acute renal failure is associated with a high mortality rate, a prolonged hospitalization and an impaired drug excretion.

In many hospitals a protocol on contrast media safety is issued to identify high risk patients. Preventive measures are taken in high risk patients. These include hydration and stopping nephrotoxic medication if possible. The incidence in non-hospitalized patients despite preventive measures is not well known. This study will estimate the incidence of CIN in this population.

The definition of CIN is an increase of serum creatinine of at least 44 micromole/l or a relative increase of at least 25% from baseline within 3 days after intravenous contrast administration without another aetiology to explain the increase.

Renal function is best estimated by the glomerular filtration rate (GFR). The GFR can not be measured directly. It is estimated using the 4-point Modified Diet in Renal Disease (MDRD) formula, which take ages, sex, ethnicity and serum creatinine into account. Serum creatinine is subject to variation in production and secretion, thus making GFR estimation inaccurate. In this study the possible correlation between CIN, microalbuminuria and microglobulinuria will be evaluated.

Adding more sensitive biomarkers microalbuminuria and microglobulinuria to serum creatinine can provide information on the exact mechanism of renal damage and the identification of high risk patients.

Study objective

The aim of the current study is to:
1. Determine the incidence of CIN after introduction of preventive measures.
2. Describe changes in the course of biomarkers serum creatinine, microalbumin and microglobulin related to intravenous ICM administration.
3. Compare microalbumin and microglobulin values between the identified high risk and non-high risk group before ICM administration.
4. Describe the possible correlation between the amount of ICM administered intravenously and the incidence of renal damage and CIN.

Study design

This is a single-centre, prospective, observational study.

Study burden and risks

Patients will be asked for a blood and urine sample before and between day 2 and 4 after administration of iodinated contrast media. The blood sample consist of one venous punction. The patient will be asked to collect a first morning urine sample.
This sampling is associated with a minimal patient risk and burden.

The patient group will benefit from the results of this study because of the better understanding of the mechanism of CIN. The individual patient could benefit in terms of early discovery of renal dysfunction. If renal dysfunction is established, the patient will be consulted by a nephrologist.

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 above 18 years of age and not admitted to the hospital at the time of informed consent.
- Patients scheduled for an ICM enhanced CT scan.

Exclusion criteria

Haemodialysis

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-02-2009
Enrollment:	1068
Type:	Actual

Ethics review

Approved WMO

Date:	23-12-2008
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL24538.094.08