

The evaluation of renal damage caused by iodinated contrast media used to enhance images in computer tomography scanning by assessing multiple serum and urinary parameters.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19883

Source

NTR

Brief title

CINEMA study

Health condition

contrast induced nephropathy
renal damage caused by iodinated contrast media (ICM)

Sponsors and support

Primary sponsor: n.a.

Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Incidence of CIN

Secondary outcome

- Microalbuminuria
- Microglobulinuria

Study description

Background summary

Brief summary CINEMA study:

Iodinated contrast media (ICM) are administered in a large percentage of Computer Tomography (CT) scans to evaluate enhancement of normal and pathological 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 $44 \mu\text{mol/l}$ or a relative increase of at least 25% from baseline within 3 days after intravenous contrast administration without another etiology 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 caused by ICM and possible prophylactic measures.

Study objective

1. Pre- and post-hydration using a sodium bicarbonate infusion scheme is an effective method to prevent CIN from occurring.
2. The current protocol is efficient in identifying high risk patients.
3. Microalbuminuria and microglobulinuria can provide sensitive and specific information on microscopic renal damage caused by ICM.
4. The course of microscopic renal damage caused by ICM on glomerular and tubular level can be evaluated using microalbuminuria and microglobulinuria.
5. There is a correlation between the amount of ICM per kilogram body weight and the incidence of CIN.

Study design

Assessment of renal function 0-7 days before ICM administration and 2-4 days after ICM administration.

Total number of patients to be included in appr. 3-6 months.

Intervention

Additional sampling of blood and urine in out-hospital patients within one week before ICM administration and within 2-4 days after ICM administration

Contacts

Public

Medisch Centrum Alkmaar

Hylke Jan Kingma
Alkmaar
The Netherlands
+31 (0)72 5483563

Scientific

Medisch Centrum Alkmaar

Hylke Jan Kingma
Alkmaar
The Netherlands
+31 (0)72 5483563

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

1. Haemodialysis

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2008
Enrollment:	1068
Type:	Anticipated

Ethics review

Not applicable

Application type:

Not applicable

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
NTR-new	NL1413
NTR-old	NTR1473
Other	METC Noord-Holland : M08-056
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

The results of the CINEMA study will be published in a peer-reviewed journal