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.

Gepubliceerd: 03-10-2008 Laatst bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19883

Bron
Nationaal Trial Register

Verkorte titel
CINEMA study

Aandoening

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

Ondersteuning

Primaire sponsor: n.a.
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Incidence of CIN

Toelichting onderzoek

Achtergrond van het onderzoek

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 ƒÝmol/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.

Doel van het onderzoek

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.

Onderzoeksopzet

Assessment of renal funtion 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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Haemodialysis

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2008
Aantal proefpersonen:	1068
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1413
NTR-old	NTR1473
Ander register	METC Noord-Holland : M08-056
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

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