Risk prediction of Contrast-Induced Nephropathy

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To investigate the incidence of CIN in three hospitals where patients are treated according to the current guidelines, to identify the prediction risk factors and toobtain blood and urine samples that will allow future identification and evaluation...

Ethical review Approved WMO **Status** Recruiting **Health condition type** Nephropathies

Study type Observational non invasive

Summary

ID

NL-OMON35012

Source

ToetsingOnline

Brief title

Risk Contrast-Induced Nephropathy

Condition

Nephropathies

Synonym

kidneydamage because of contrast

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

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

Intervention

Keyword: Biomarkers, Contrast induced nephropathy (CIN), Incidence, Risk factors

Outcome measures

Primary outcome

Incidence of CIN in patients treated according to the current guidelines, risk

factors associated with CIN, accuracy of selected biomarkers

Secondary outcome

none

Study description

Background summary

Contrast media are frequently used in diagnostic and therapeutic procedures. Acute renal failure is still a regular and severe complication seen after administration of intravascular iodinated contrast media.

This contrast-induced nephropathy (CIN) (defined as a rise of serum creatinine > 25% within 48 to 72 hours after administration,) is associated with marked morbidity and mortality.

It is therefore important to recognize the patients at risk and to take appropriate preventive measures.

Study objective

To investigate the incidence of CIN in three hospitals where patients are treated

according to the current guidelines, to identify the prediction risk factors and to

obtain blood and urine samples that will allow future identification and evaluation of

biomarkers for the early detection of CIN.

Study design

multi-centre prospective cohort study

Study burden and risks

There are no major associated risks resulting from filling in the questionnaire and by taking two additional blood sample and two additional urine samples per person, compared to standard procedure.

Contacts

Public

Universitair Medisch Centrum Sint Radboud

Hatertseweg 299 6533 AK Nijmegen NL

Scientific

Universitair Medisch Centrum Sint Radboud

Hatertseweg 299 6533 AK Nijmegen NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Adult patients (>18 yrs) with an estimated GFR<60ml/min, who are scheduled for an elective procedure that involves the intravascular administration of iodinated contrast media

Exclusion criteria

Age <18, the inability to provide written informed consent, GFR >60ml/min

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 25-07-2011

Enrollment: 4500

Type: Actual

Ethics review

Approved WMO

Date: 26-10-2010

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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 NL31607.091.10