Oral versus Intravenous Hydration to Prevent Contrast Induced Nephropathy

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To investigate if home-hydration is a non inferior alternative for in-hospital hydration in the prevention of Contrast Induced Nephropathy in high risk patients.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON37218

Source
ToetsingOnline

Brief title
Oral versus Intravenous Hydration to Prevent Contrast Induced Nephropathy

Condition

- Nephropathies

Synonym
contrast-induced nephropathy/ kidney damage after contrast administration

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: contrast-induced nephropathy (CIN), oral hydration, prevention, randomized

controlled trial

Outcome measures

Primary outcome

The primary endpoint will be the ratio between the 48-72 hours creatinine

levels and

the baseline levels.

Secondary outcome

In addition, we will evaluate the incidence of contrast nephropathy in the

groups

Defined as a rise in serum creatinine of >=25% or >=44umol/L 48-72 hours after

contrast administration.

Finally, the incidence of adverse event will be evaluated. And patient

satisfaction.

Study description

Background summary

Contrast media are frequently used in diagnostic and therapeutic procedures. Although replacement of high osmolar iodinated contrast media by low osmolar non-ionic contrast media has reduced the number of adverse events, acute renal failure is still a regular and severe complication seen after intravascular administration of iodinated contrast media.

This contrast-induced nephropathy (CIN), defined as a rise of serum creatinine >= 25% or >=44 umol/L within 48 to 72 hours after administration of contrast media, is associated with marked morbidity and mortality.
In 2007, CBO guidelines for the prevention of CIN have been developed.
(CIN is also one of the targets of the Dutch Ministry of health/VMS safety program.)
All patients are screened for risk factors, which includes measurement of renal function by estimating glomerular filtration rate (eGFR) using the MDRD formula.

High risk patients are admitted to the hospital for treatment with intravenous saline for a period of 8-24 hours. Between 48-72 hours after the procedure their renal function is checked.
This approach has a large impact on health care resources.
The total number of procedures with contrast media amounts approximately 1 million/year in the Netherlands and is expected to increase in the nearby future.
Following the guideline approximately 10% of patients will be admitted for in-hospital intravenous hydration. The total number of hospital days needed for this strategy amounts approximately 180.000/year.

This proposal evaluates an alternative procedure for the prevention of CIN. The alternative procedure involves home-hydration with salt tablets, under supervised care with monitoring of diuresis and body-weight , and should reduce the need for hospitalisation of the patients.

In two small RCT*s it was shown that home hydration may be as effective as intravenous hydration. The largest study involved 76 patients per arm, and observed an incidence of CIN of 5.2% after hospital hydration and 6.6% after home hydration using oral administration of salt capsules. Due to low numbers of patients a difference of 10% between the groups cannot be excluded.

We expect that effective home hydration will almost completely eliminate the need for hospitalisation for elective procedures. The new procedure will save costs, but also limit the use of scarce hospital capacity. In addition, it is hypothesized that patient satisfaction and quality of life increases in the home hydration setting.

Study objective

To investigate if home-hydration is a non inferior alternative for in-hospital hydration in the prevention of Contrast Induced Nephropathy in high risk patients.

Study design

multi-centre randomized controlled trial

Intervention

Arm A: sodium chloride 1g/10kg of body weight /day per os on day -2 and -1 before contrast exposure. (maximum of 10 gram per day in case of obesitas)
Arm B (standard procedure): Nacl 0.9% total 1000ml in 4 hrs or (in case of heart failure or severe renal failure) 12 hrs before and in 4 or in 12 hrs after contrast administration.

Study burden and risks

Patients who are randomized for home hydration will receive salt tablets and start 48 hrs before the procedure. The risk of taking salt tablets is low, there are some reports of nausea. Because we exclude patients who have decompensated heart failure the use of these amounts of salt is considered safe and we do not expect signs of overhydration. We monitor this by a telephone consult, 24 hours after the intake of the first tablets. Body weight and intake of tablets will be monitored. Before contrast administration a blood and urine sample will be taken.
Patients who are randomized for intravenous hydration will be admitted and will receive standard treatment for high risk patients with the addition of one blood and urine sample taken before contrast administration.These patients will also be asked to participate in our study *Risk prediction of Contrast-Induced Nephropathy* 31607 (ARB)
In all patients 48-72 hours after contrast administration a blood sample is taken to check for the development of CIN, this is standard treatment according to the guidelines.
We will ask all patients to fill in a questionnaire on patient satisfaction.

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

Adult patients >18 years undergoing an elective procedure involving intravascular administration of iodinated contrast media and at high risk for the development of Contrast Induced Nephropathy (as defined by guideline criteria).
High Risk (HR)
eGFR<45ml/min/1.73m2
eGFR<60ml/min/1.73m2 and diabetes mellitus
eGFR 45-60 ml/min/1.73m2 and >= 2 risk factors:
- Peripheral Arterial Disease
- Heart Failure
- Age >75 yrs
- Anemia (Ht <0.39* and <0.36*)
- Dehydration
- Use of diuretics and/or NSAID*s
- Symptomatic hypotension
- High volume contrast >150ml
- Cardiological intervention
eGFR<45ml/min/1.73m2

Exclusion criteria

Age <18 years
Low risk for the development of CIN, therefore no need for hydration (see table).
Emergency contrastprocedure.
Overt signs of overhydration; orthopnea or pulmonal rales at the time of the first consult.
Double or triple diuretic use for pre-existing heart failure.
Severe renal failure (CKD stage V eGFR<15ml/min/1.73m2)
Multiple Myeloma.
Repeated contrast exposure <2 weeks
Unstable serum creatinine >25% change <6 weeks
The inability to provide written informed consent.
Participation in another intervention study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-08-2012
Enrollment:	2200
Type:	Actual

Ethics review

Approved WMO

Date:	18-07-2012
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	NL40730.091.12