Sodium Bicarbonate versus Saline for the prevention of Contrast Induced Nephropathy in patients undergoing angiography

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Evaluation of the rise in serum creatinine and the incidence of CIN following angiography in patients treated with a short hydration regime during 1 hour with sodium bicarbonate compared to a hydration regime with saline during 6-24 hours.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON37953

Source
ToetsingOnline

Brief title
The Helios Study

Condition

- Nephropathies
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
contrast induced nephropathy, contrast medium induced nephropathy

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Aanvraag voor subsidie moet nog geschieden. Zal bij ZONMW gedaan worden.

Intervention

Keyword: acute kidney injury, Angiography, Contrast induced nephropathy, hydration

Outcome measures

Primary outcome

• mean rise in serum creatinine 2-4 days after angiography

Secondary outcome

• CIN defined as an increase in serum creatinine > 25% or > 44 µmol/l after 2-4

days;

• CIN defined as an increase in serum creatinine > 25% or > 44 µmol/l after 2

months;

• Indication for dialysis due too CIN;

• Congestive heart failure due to rapid volume expansion with an indication for

treatment with diuretics.

Study description

Background summary

Contrast induced nephropathy (CIN) can occur after injection of radiographic low osmolar contrast media, which are frequently used for angiography. Patients with renal impairment, as specially in combination with diabetis mellitus are at risk for developing CIN. In the majority of the patients renal function will recover within two months after the diagnosis of CIN.
A consensus of the CBO (Dutch Central Guidance Institute) advises to give patients at risk for CIN a pre and post hydration treatment each during 3-12 hours with 0.9% NaCl 1000 mL. This results in a maximum of two days

hospitalization for a large group of patients. An alternative hydration regime is a short regime with sodium bicarbonate 1.4% 3 ml/hour/kg bodyweight, 1 hour prior and 6 hours after angiography. This hydration regime is studied in patient groups undergoing coronary angiography. There is no consensus on the exact implantation of hydration regimes with sodium bicarbonate and post hydration might not be necessary.

Study objective

Evaluation of the rise in serum creatinine and the incidence of CIN following angiography in patients treated with a short hydration regime during 1 hour with sodium bicarbonate compared to a hydration regime with saline during 6-24 hours.

Study design

This is a prospective multi-center cohort study.

Intervention

• Group 1: Pre hydration with sodium bicarbonate 1.4% 250 mL 1 hour prior to angiography.
• Group 2: Pre and post hydration with saline 0.9% 1000 ml each during 3-12 hours.

Study burden and risks

The amount of stress on the patient for this study is very limited.
Renal function is routinely measured prior to angiography. In this study patients will receive one extra vena punction prior to and 4 hours after angiography and are asked for urine samples. However, when possible, blood work will be extracted from the IV needle to spare a patient from extra vena punctions.
The CBO advises to check renal function 2 to 4 days after angiography of all patients at risk for CIN. During this routine check we will ask for one extra serum sample (10 ml).
If renal function is decreased after 2 to 4 days according to the definition of CIN, patients are asked to come back after 2 months for some extra blood work to determine whether their kidney function is restored. This is not clinical practice. Participation in this study results in 1 extra hospital visit if CIN is diagnosed after 2 to 4 days. Patients will probably have advantage of this accurate monitoring of renal function.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- patients undergoing angiography with intra arterial contrast administration
- eGFR (estimated glomerular filtration rate) < 60 ml/min

Exclusion criteria

- age < 18 years
- heamodynamic instability
- pregnancy
- allergy for contrast media

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:	Recruitment stopped
Start date (anticipated):	03-12-2010
Enrollment:	346
Type:	Actual

Ethics review

Approved WMO Date:	13-12-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	01-12-2011
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	23-01-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	08-03-2012
Application type:	Amendment

Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	02-05-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	04-06-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	18-07-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29385
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL33992.058.10