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

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• Evaluation of the incidence of CIN after CT-angiography with a hydration regime during 1 hour with sodium bicarbonate compaired to a hydration regime with saline during 24 hours.• Furthermore the risk for developing CIN after CT-angiography is...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Interventional

Summary

ID

NL-OMON38407

Source
ToetsingOnline

Brief title
The Saliña study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Nephropathies

Synonym
acute renal failure following contrast injection, Contrastnephropathy

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Aanvraag subsidie moet nog geschieden. Zal bij de nierstichting gedaan worden.

Intervention

Keyword: Contrast Induced Nephropathy, CT-angiography, Hydration, Prevention

Outcome measures

Primary outcome

• CIN defined as an increase in serum creatinine > 25% or > 44 µmol/l after 3-5

days.

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

months or an indication for dialysis.

Secondary outcome

• loss of renal function, calculated as an absolute decrease in eGFR.

Study description

Background summary

Contrast induced nephropathy (CIN) can occur after injecting radiographic low osmolair contrast media, which is used for CT-angiography. Patients with renal impairment, as specially in combination with diabetis mellitus are at risk for developing CIN. In most of the patients renal function recovers in 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 posthydration treatment each during 12 hours with 0.9% saline 1 ml/hour/kg bodyweight. This results in two days hospitalisation 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 CT-angiography. This hydration regime is studied in patient groups undergoing coronairy angiography.

There is no consensus of the exact implemtation of hydration regimes with sodium bicarbonate.

Study objective

• Evaluation of the incidence of CIN after CT-angiography with a hydration regime during 1 hour with sodium bicarbonate compaired to a hydration regime with saline during 24 hours.
• Furthermore the risk for developing CIN after CT-angiography is studied for both hydration regimes.

Study design

This is a prospective multi-center cohort study.

Intervention

• Group 1: Prehydratie with sodium bicarbonate 1.4% 3 ml/kg bodyweight 1 hour prior to CT-angiography.
• Group 2: Pre- and posthydration with saline 0.9% 1 ml/hour/kg bodyweight both during 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 CT-angiography. In this study patients will receive one extra vena punction prior to CT-angiography and are asked for one urine sample after CT-angiography.

The CBO advises to check renal function 3 to 5 days after CT-angiography of all patients at risk for CIN. In this study we will ask for one extra venapunction and urine sample after 3 to 5 days and one extra venapunction after 8 days.

If renal function is decreased after 3 to 5 days according to the defenition of CIN, patients are asked to come back after 2 months for some extra bloodwork to determine whether there kidney function is restored or not. This is not clinical practice.

Participation in this study results in 1 extra hospital visit if CIN is diagnosed after 3 to 5 days. After 8 days one extra venapuncture is asked. Patients will probably have advantagde of this accurate monitoring of kidney function.

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

eGFR < 45 ml/min
eGFR < 60 ml/min and diabetis mellitus

Exclusion criteria

- age < 18 years;
- exposure to radiographic contrast media within 7 days;
- pregnancy;
- allergy for low osmolar contrast media.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2010
Enrollment:	547
Type:	Actual

Ethics review

Approved WMO Date:	21-09-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	15-02-2012
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: 21374
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL27494.058.09
OMON	NL-OMON21374