Cardiologic prophylaxis for Contrast Induced Nephropathy (CARCIN-trial)

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Assess if CIN prophylaxis for CTA and a TAVI procedure with a 1 -hour sodium bicarbonate protocol is non-inferior in terms of decline in eGFR and serum creatinine level to the 24 hour saline protocol. in pre-operative screening for TAVI and actual...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	Observational invasive

Summary

ID

NL-OMON43732

Source
ToetsingOnline

Brief title
CarCIN-trial

Condition

- Cardiac valve disorders
- Nephropathies

Synonym
Contrast-induced-nephropathy, kidney failure

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Contrast induced nephropathy, prehydration, TAVI

Outcome measures

Primary outcome

The level of serum creatinine and eGFR 2-5 days (48-120 hours) after contrast administration compared to pre-contrast baseline serum creatinine.

Secondary outcome

• Occurrence of CIN (Contrast Induced Nefropathy, defined as an increase of serum creatinine >25% or 44.2 µmol/l within 2-5 days according to international definitions for AKI.

• Level of increase of NT-proBNP in serum

• Self-reported level of dyspnoea using the BORG-CR10 scale compared before and after hydration

Study description

Background summary

In preoperatieve screening for transcatheter aortic valve implantion (TAVI), contrast enhanced computed tomography angiography (CTA) is performed as standard imaging technique with administration of contrast agent. In patients with an impaired kidney function defined as a the administration of contrast agents is associated with contrast induced nephropathy (CIN). To prevent CIN, patients with impaired kidney function get in-hospital CIN prophylaxis, consisting of 24 hour hydration with saline. In patients with aortic stenosis or heart failure however, the administration of excessive amounts of fluid can result in hypervolemia resulting in pulmonary oedema. Recent studies in general patients show that a 1 hour hydration protocol with sodium bicarbonate is non-inferior to the widely used 24 hour saline protocol.

The TAVI population is characterized by a high age with a decreased renal

function due to ageing without a nephropathy.

Study objective

Assess if CIN prophylaxis for CTA and a TAVI procedure with a 1 -hour sodium bicarbonate protocol is non-inferior in terms of decline in eGFR and serum creatinine level to the 24 hour saline protocol. in pre-operative screening for TAVI and actual procedure.

Study design

The study is designed as a single center open label prospective randomized controlled non-inferiority trial.
Arm 1: 24 hour NaCl 0.9%, 1 ml/kg/hour
Arm 2: 1 hour Sodiumbicarbonate 1.4%, 3 ml/kg/hour

Study burden and risks

This study will provide us insight in the effectiveness of the saline arm and the bicarbonate as CIN-prophylaxis in the TAVI-patient group. This is of significant importance since this is an increasing patient group in an ageing population and advances in the absolute number of TAVI procedures performed worldwide. Benefits of a shorter and low-volume hydration protocol are an assumed decreased risk of pulmonary oedema and reduction in admission time.

Patients will be asked to collect two urine samples. An extra blood sample will be taken 2-5 days after contrast administration. This blood sample can be taken at the AMC or arranged by the patients general practitioner, according to patients preference. Current guidelines already advice to follow-up renal function by means of a blood sample. Furthermore a self-reported level of dyspnea will be asked at five timepoints. Patients randomized in the saline arm will receive standard care. Patients randomized in the bicarbonate arm will get the short 1-hour hydration prophylaxis. There is no difference in admission time for the TAVI procedure. Patients in the saline arm will be admitted one day and night at the timepoint of the CTA whereas patients admitted in the bicarbonate arm will not. There is no difference in admission prior to the TAVI procedure.

Patients will probably have advantage of the 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

Patient is planned for Contrast enhanced CT and/or TAVI-procedure
eGFR < 60 ml/min/1.73m^2
written informed consent

Exclusion criteria

M. Kahler / M. Waldenström

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	15-12-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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: 25782
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50955.018.14
OMON	NL-OMON25782