Preventing contrAst induced Nephropathy after TranscathEter aortic valve Replacement

Published: 15-09-2016
Last updated: 16-04-2024

To evaluate the efficacy of 250ml 1.4% sodium bicarbonate versus hypotone saline hydration prior to TAVI in patients with CKD to prevent CIN.

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

Summary

ID

NL-OMON43053

Source
ToetsingOnline

Brief title
PANTER

Condition

- Cardiac valve disorders
- Nephropathies

Synonym
aortic stenosis, kidney injury

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: in eerste instantie vanuit eigen budget

Intervention

Keyword: Contrast, Kidney injury, Prehydration, Transcatheter Aortic Valve Replacement (TAVR)

Outcome measures

Primary outcome

1. Primary efficacy outcome is the development of contrast-induced nefropathy

(CIN).

2. Primary safety outcome is the development of acute heart failure due to

volume expansion.

Secondary outcome

1. Occurrence of the composite of CIN or acute heart failure due to volume

expansion.

2. Maximal relative change in serum creatinine measured between 0 and 72 h

post-TAVI compared with baseline.

3. Incidence of acute kidney injury, according to AKIN classification.

4. The need for dialysis.

5. The need for and number of blood transfusions.

6. Length of hospital stay.

7. Recovery of renal function in CIN patients [recovery defined as an increase

in serum creatinine <25% or <44 µmol/L (0.5 mg/dL) measured at 1 month

post-TAVI compared with baseline]

Study description

Background summary

Chronic kidney disease (CKD) and (subsequent) acute kidney injury are frequent in patients undergoing transcatheter aortic valve implantation (TAVI). Moreover, these patients are easily hypervolemic and susceptible for cardiac decompensation. Prevention of contrast induced nephropathy (CIN) has not yet been studied in these patients, and evidence on different strategies is urgently needed.

Study objective

To evaluate the efficacy of 250ml 1.4% sodium bicarbonate versus hypotone saline hydration prior to TAVI in patients with CKD to prevent CIN.

Study design

Randomized controlled trial.

Intervention

Random 1:1 allocation to sodium bicarbonate 250mL 1 h before TAVI versus hypotone saline 1 ml/kg/h for 12 h before and 12 h after TAVI.

Study burden and risks

Follow-up is 30 days. We expect no physical and/or psychological discomfort associated with participation.

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

1. Patient has provided written informed consent.
2. Patient is undergoing TAVI.
3. Patient has an estimated GFR <60ml/min/1.73m2.

Exclusion criteria

1. Patient has end-stage kidney disease requiring dialysis.
2. Emergent TAVI (planned before next working day).
3. Recent exposure to radiographic contrast agents (within 2 days prior to the TAVI).
4. Allergy to contrast agent.
5. Planned administration of dopamine, mannitol, fenoldopam or N-acetylcysteine during the intended time of the study.
6. Need for continuous hydration therapy (e.g. sepsis).
7. Multiple myeloma.
8. Contra-indication to sodium bicarbonate.

Study design

Design

Study phase:	4
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):	03-10-2016
Enrollment:	200
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Saline 0.65%
Generic name:	Sodium Chloride
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Sodium Bicarbonate 1.4%
Generic name:	Sodium Bicarbonate
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	15-09-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
EudraCT	EUCTR2016-001919-20-NL
CCMO	NL57734.100.16