The Compass Trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29471

Source
NTR

Health condition

contrast induced acute kidney injury (CI-AKI)

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Leiden University Medical Center

Intervention

Outcome measures

Primary outcome

Mean relative increase in serum creatinine.

Secondary outcome

1. Incidence of CIN;

2. Recovery of renal function 2 months after CT in patients who developed CIN;

3. Mean relative increase in serum creatinine 7-14 days after contrast administration;

4. Acute kidney injury according to the serum creatinine based RIFLE criteria;

5. The need for dialysis;

6. (Re)hospitalisation, duration of hospitalisation in the two months following randomisation;

7. Visits to the outpatient clinic in the two months following randomisation.

Study description

Background summary

Contrast induced nephropathy (CIN), an acute decline in renal function, may occur following intravenous iodinated contrast media-enhanced CT. In the majority of patients, CIN is a reversible condition with full recovery of renal function within two months. The CBO guideline recommends preventive hydration in patients at high risk for the development of CIN (high risk defined as estimated kidney function (eGFR) <45 mL / min OR eGFR 45-60 ml / min in combination with comorbidities also at risk of CIN). The standard preventive treatment recommeded by the CBO guideline consists of intravenous hydration with 1000 ml 0.9% of saline infused within 3-12 hours prior to and after contrast administration is. The implementation of the CBO guideline in clinical practice is expensive due to the hospitalisation that is needed for preventive hydration (yearly cost in the Netherlands : 25.9-39.0 million).
Previously, a randomized trial was conducted which showed that one-hour prehydration with sodium bicarbonate is non-inferior to pre-and posthydration with saline in patients with chronic kidney disease undergoing intravenous contrast media-enhanced CT. The use of sodium bicarbonate pre-hydration stronlgy reduced health care costs (by 66%) associated with preventive hydration, as it does not require hospitalisation but could place in daycare or even an outpatient setting.

The risk of CIN or irreversible kidney damage is very limited, especially in the group of patients with moderate renal impairment (estimated renal clearance 30-60 ml / min). However, this patient group forms the majority of patients with an indication for CIN preventive hydration. A recently published meta-analysis showed renal function to be reduced at two months post CT in only 1.1% of patients, and 0.06% of patients undergoing CT had a (temporarily) need for dialysis. Other studies showed a risk of CIN of 0-2% in patients with moderate renal impairment when preventive hydration is applied. Therefore, preventive hydration might not even be necessary in patients with moderate renal impairment. Reducting eGFR cut-off levels for preventive hydration to an eGFR <30 ml /min could result in about 70% extra savings in healthcare costs for preventive hydration.

Objective of the study:

To study whether the existing eGFR cut-off levels for preventive hydration of < 45 ml/min or between 45-60 ml/min in combination of other comorbidity at risk of CIN can be safely lowered to an eGFR < 30 ml/min, regarsless of the presence of other risk factors for the development of CIN.

Study design:

Open label, non-inferiority randomized trial.

Study objective

CI-AKI preventive hydration is not needed in patients with a creatinine clearence between 30-60 ml/min undergoing intravenous contrast media-enhanced CT.

Study design

Baseline, 2-4 days, 7-14 days, and 2 months post CT.

Intervention

Randomisation in a 1:1 ratio to:

1. 1 hour prehydration with 250 ml 1.4% sodium bicarbonate;

2. No preventive hydration.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with an eGFR (estimated glomerular filtration rate 30-45 ml/min);

2. Patients with an eGFR 45-60 ml/min and diabetes mellitus (either type 1 or 2);

3. Patients with an eGFR 45-60 ml/min and at least two of the following: Peripheral artery disease, congestive heart failure, age > 75 years, anemia, contrastvolumes > 150 cc or the use of nephrotoxic medication;

4. Informed consent.

Exclusion criteria

1. eGFR < 30 ml/min;

2. Age < 18 years;

3. Patients with other intravenous contrast administrations (including intravenous contrast enhanced MRI) < 7 days of study CT-scan OR in 5 days following study CT-scan;

4. Pregnancy;

5. Renal transplantation in the last 3 years;

6. Previous participation to the Compass trial;

7. Dehydrated patients (systolic blood pressure < 100 mmHg);

8. Proven instable renal function in the four weeks prior to randomisation (increase or decrease in serum creatinine > 20%);

9. Known allergy for iodinated contrast media.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2013
Enrollment:	575
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-12-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39573
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3605
NTR-old	NTR3764
CCMO	NL42723.058.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39573

Study results

Summary results
N/A