The Compass Trial.

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29471

Bron
NTR

Aandoening

contrast induced acute kidney injury (CI-AKI)

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Leiden University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Mean relative increase in serum creatinine.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Randomisation in a 1:1 ratio to:

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

2. No preventive hydration.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2013
Aantal proefpersonen:	575
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-12-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39573
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Register	ID
OMON	NL-OMON39573

Resultaten

Samenvatting resultaten
N/A