A randomized trial to increase the efficiency of the prevention of contrast induced acute kidney injury. The Compass trial

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON39573

Source
ToetsingOnline

Brief title
The Compass Trial

Condition

- Nephropathies

Synonym
contrast induced acute kidney injury, contrast induced nephropathy

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,Aanvraag tot subsidie is gedaan bij Fonds NutsOhra. Of deze subsidie wordt toegekend is op dit moment nog niet bekend.

Intervention

Keyword: chronic kidney disease, contrast induced acute kidney injury, CT-scan, Prevention

Outcome measures

Primary outcome

- Mean relative increase in serum creatinine

Secondary outcome

- incidence of CIN

- recovery of renal function 2 months after CT in patients who developed CIN

- mean relative increase in serum creatinine 7-14 days after contrast

administration

- acute kidney injury according to the serum creatinine based RIFLE criteria

- the need for dialysis

- (re)hospitalisation, duration of hospitalisation in the two months following

randomisation

- 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.

Study objective

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, multi-center, non-inferiority, randomized trial

Intervention

Randomisation in a 1:1 ratio to:
- 1 hour prehydration with 250 ml 1.4% sodium bicarbonate
- No preventive hydration

Study burden and risks

The extent and nature of the burden for patients participating to the Compass Study is very limited. In current daily practice, serum creatinine is measured prior to CT. During the Compass Study, serum creatinine measurement will be accompanied by the drawing of one extra serum sample.Furthermore, serum and urine samples will be taken 4-6 hours and 3 and 7-10 days post CT. Serum samples will be collected via the i.v. needle, if possible, which reduces the amount of venipunctures. Moreover, patients will be asked for a urine sample prior to and after CT-scan

The CBO-guideline advises to measure renal function 3 days post CT in patients with chronic kidney disease. Therefore, the venapuncture at 3 days post CT is not of extra burden for the patients. Furthermore, renal function will be measured 2 months post CT in patients who have had developed CIN to analyse whether renal function has recovered.

Particapation to the Compass Trial will result in one extra visit to the hospital for most patients and a maximum of two extra visits for patients developing CIN. However, the patient probably has advantages of this strick controll of renal 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

- patients with an eGFR (estimated glomerular filtration rate 30-45 ml/min)
- patients with an eGFR 45-60 ml/min and diabetes mellitus (either type 1 or 2)
- 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
- informed consent

Exclusion criteria

- eGFR < 30 ml/min
- Age < 18 years
- 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
- pregnancy
- renal transplantation in the last 3 years
- previous participation to the Compass trial
- dehydrated patients (systolic blood pressure < 100 mmHg)
- proven instable renal function in the four weeks prior to randomisation (increase or decrease in serum creatinine > 20%)
- known allergy for iodinated contrast media

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-04-2013
Enrollment:	575
Type:	Actual

Ethics review

Approved WMO Date:	02-04-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	05-06-2013
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: 29471
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL42723.058.12
Other	NTR nummer 3764
OMON	NL-OMON29471