Furosemide forced diuresis with matched hydration vs Standard care of treatment in the prevention of contrast mediated nephropathy (CIN) due to percutaneous transluminal angioplasty (PTA): a randomized controled trial

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The objective of the study can be defined into two goals1. Reduction of CIN using the Renalguard with furosemide forced diuresis in patients known with chronic kidney failure whom require an endovascular intervention of the lower limbs. 2. Early...

Ethical review	Approved WMO
Status	Pending
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON43281

Source
ToetsingOnline

Brief title
Furosemide forced diuresis vs. standard car of treatment

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
narrowing of the arteries, Peripheral artery disease

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Contrast induced nephropathy, Furosemide, Percutaneous transluminal angioplasty, Renalguard

Outcome measures

Primary outcome

1. Incidence of CIN after successful endovascular procedure 1,3 and 30 days postoperative (defined as a rise of >25% or >0.5mg/dL serum creatinine when compared with the baseline values).

2. Rising level of urine biomarkers after successful endovascular procedure. Defined as an area under the curve ROC (AUC ROC) > 0.7, measured on the recovery after PTA to diagnose CIN. The rise of biomarkers is compared to the rise of serum creatinine to detect CIN (rise of serum creatinine >0.5mg/dL or more than 25% increase after 48-72h when compared to the baseline values).

Secondary outcome

Complication secondary to CIN prophylactic therapy

- Dialysis due to CIN

- Acute pulmonary oedema

Post-operative in-hospital adverse events

- Acute myocardial infarction

- Death

Hospitalisation duration in days

Postoperative complication that manifest themselves after hospital discharge, which require additional care. Such as; seroma, wound infection, false aneurysm, and re-occlusion or re-stenosis within 4 weeks after the intervention. The surgeon will actively ask the patients whether complications occurred after hospital discharge, when the patient will present themselves in the outpatient clinic after 4 weeks.

Study description

Background summary

Recent publications regarding the Renalguard showed a reduction in the incidence of CIN among patients who received a PCI and where known with chronic kidney failure. This study indicates that this relatively new technique is safe and effective in the prevention of CIN. Marenzi et al. showed that the use of the Renalguard in 87 patients is not associated with device related complications. In this study an absolute reduction of 75% was evident in the incidence of CIN, when compared to regular pre-hydration therapy (4.6% vs 18%). These studies where all conducted in cardiac patients requiring endovascular treatment. Up to now there are no randomised studies studying hydration therapy with the Renalguard in patients with renal function impairment whom require endovascular treatment of the lower limbs.

We hypothesise the following;
1. Lowering the incidence of contrast induced nephropathy is possible when the diuresis is increased up to >300 ml/hour during the intervention (PTA) and is continued up to 4hours after the revascularizing procedure, using furosemide matched hydration aided by the the Renalguard.

2. The development of CIN can be detected in an early stage by detecting certain urine biomarkers postoperative on the general ward, whereas diagnosing CIN is nog possible after 72h postoperative in the detection of increased serum creatinine.

Endpoints regarding;
Hypothesis 1.
Primary (clinical) success is defined as a 50% reduction in contrast induced

nephropathy (CIN) using the Renalguard combined with furosemide forced diuresis.
Secondary outcomes are the CIN related adverse events, in-hospital events such as; acute pulmonic oedema, cardiogenic shock, additional treatment due to CIN and the mortality within 1 month.

Hypothesis 2.
Primary success is defined as an area under de curve greater than 0.70 of the urine biomarkers for early detection of CIN.
Secondary we will determine the optimal cut-off point for the detection of CIN with the biomarkers and calculate the sensitivity and specificity.

Study objective

The objective of the study can be defined into two goals

1. Reduction of CIN using the Renalguard with furosemide forced diuresis in patients known with chronic kidney failure whom require an endovascular intervention of the lower
limbs.
2. Early detection of CIN by sampling the urine biomarkers; NGAL, KIM-1 and IL-18 15 minutes after ending the revascularizing procedure on
the general ward. Comparing to the golden standard in detecting CIN, rise of serum creatinine 72h after surgery.

To summarize, the aim of this study is to verify if the incidence of CIN can be reduced by using the Renalguard with furosemide forced diuresis in patients with chronic kidney failure who receive an endovascular intervention, when compared to the standard care of treatment.
Secondly we would like to study whether certain urine biomarkers can detect CIN in an early stage. The urine biomarkers that will be used are; NGAL, KIM-1 and IL-18. We will evaluate if increase in these urine biomarkers postoperatively are predictive in the development of CIN diagnosed 72hours postoperatively using serum creatinine.

Study design

The previously mentioned study and hypothesis gave rise to the following study design. The study is designed as an open randomised controlled trial. Blinding of patient or investigator is nt possible. Pre-operative the patient will sign the informed consent form, after which the patient will be randomised in to either one of the two groups. Group one will include patients who will receive pre- and post-hydration following hospital protocol. Group two will include patients who will be hydrated perioperative using the Renalguard system in combination with furosemide forced diuresis. An urine sample will be collected 4 hours postoperative in both groups. For further information

regarding the randomisation process I would like to refer you to paragraph 8.2 of the study protocol.

Intervention

Percutaneous transluminal angioplasty of the lower limbs. One group will receive pre-hydration as is common regarding hospital protocol. The intervention group will be hydrated perioperative using the Renalguard.

Study burden and risks

The study procedures are not related to additional burden or risks for the patients. However to increase the diuresis the patient will receive a bolus of furosemide (0.5mg/kg) and might experience some of the side-effects. The following side effect are known to occur and are published online on the *farmacotherapeutisch kompas*:

Very often (>10%): dehydration, hypovolemia, disturbance of electrolytes, increased serum creatinine, increased serum triglycerides.

Often (1-10%): haemoconcentration leading to: hypo- sodium, -potassium, or -chloride. Liver encephalopathy. Increased diuresis, increased cholesterol. Increased uric acid in serum which might lead to a gout-attack.

Not so often (0.1-1%): thrombocytopenia. Hearing impairment, such as tinnitus (often temporary), deafness (sometimes irreversible). Nausea. Itchiness, urticaria, dermal rash, erythema multiforme, bullous dermatitis, pemphigoid, exfoliative dermatitis, purpura, fotosensibilitation. Increased levels of urea in serum, decreased glucose tolerance.

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 aged 18 years or older, regardless of gender, and who are legally capable to make informed decision. The patients are diagnose with an impaired renal function and require an endovascular revascularisation of the lower limbs. The patients are diagnosed with peripheral arterial disease Fontaine IIb, III, IV.

Exclusion criteria

-hypersensitivity to furosemide
-intravenous contrast 10 days prior to intervention
-expected to receive intravenous contrast within 72h after intervention
- contra indication to receive a Foley catheter

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-01-2017
Enrollment:	180
Type:	Anticipated

Medical products/devices used

Generic name:	Renalguard
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	Furosemide (Lasix)
Generic name:	Furosemide
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	09-01-2017
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	EUCTR2016-005072-10-NL
ClinicalTrials.gov	NCT
CCMO	NL59809.096.16