Furosemide forced diuresis with Renalguard versus standard care of treatment in the prevention of contrast induced nephropathy in patient receiving a lower extremity angioplasty.

Gepubliceerd: 13-12-2016 Laatst bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20313

Bron
NTR

Aandoening

- Peripheral arterial disease (PAD)
- Contrast induced nephropathy (CIN)
- Percutaneous transluminal angioplasty (PTA)

Ondersteuning

Primaire sponsor: Zuyderland MC
Overige ondersteuning: fonds = verrichter = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Doel van het onderzoek

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 recovery, whereas diagnosing CIN is nog possible after 72h postoperative in the detection of increased serum creatinine.

Onderzoeksopzet

Urine biomarkers: 4h post intervention.

Serum creatinine: within 10 days prior to intervention, post procedure at day; 1,3,30.

Onderzoeksproduct en/of interventie

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 using furosemide forced diuresis in combination with the Renalguard.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-01-2017
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6089
NTR-old	NTR6236

Register	ID
Ander register	16-T-201 : METC Z

Resultaten