Iodinated contrast dilution in imaging lower limbs of patients with peripheral arterial disease.

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Digital subtraction angiography can be performed at a lower iodinated contrast concentration than currently used, without loss of anatomical information and image quality.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21387

Bron
NTR

Verkorte titel
IODIL

Aandoening

Peripheral Arterial Disease
Critical Limb Ischemia
Intermittent Claudication

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC) Amsterdam
Overige ondersteuning: The study is financial supported partially by GE Healthcare.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Confidence in diagnosing and treating arterial stenoses or occlusions.

Toelichting onderzoek

Achtergrond van het onderzoek

Peripheral artery disease (PAD) is a disease which encompasses patients with intermittent claudication (IC) and critical limb ischemia (CLI). Many patients with PAD are treated for peripheral artery disease with endovascular intervention. For these interventions iodinated contrast media are used. The use of these media, leads in less than ten percent of patients with normal renal function to contrast induced nephropathy (CIN), an unexplained increase in serum creatinine of more than 25% or 44 mmol/l within three days of contrast administration, and increases to 25% in patients with pre-existent impaired renal function. To reduce this risk for CIN, minimizing volume and concentration of iodinated contrast administered during digital subtraction angiography (DSA) is advocated. To our knowledge, no study has been done considering the relation between iodinated contrast concentration and volume, and the qualitative aspects of DSA in patients with PAD. Therefore, we will study the influence of contrast dilution on the confidence of the interventional radiologist in performing DSA, image quality of DSA and renal function.

Doel van het onderzoek

Digital subtraction angiography can be performed at a lower iodinated contrast concentration than currently used, without loss of anatomical information and image quality.

Onderzoeksopzet

The patient gets the intervention with the assigned contrast and 2-3 days after the procedure, blood will be withdrawn to assess renal function.

Three radiologists will score the standardized images on confidence in diagnosing and treating arterial stenoses and occlusions using a visual analogue scale. For the secondary outcome measures, the radiologists will also score image quality on a 4-point Likert Scale and eGFR will be calculated from the blood that has been drawed 2-3 days after the intervention.

Onderzoeksproduct en/of interventie

Digital subtraction angiography will be performed using the assigned iodinated contrast concentration (i.e. Omnipaque 300, 240 or 140 mg iodine/ml).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

PAD, either IC or CLI, as defined by surgeon based on patient history, with:

1. Ankle-brachial pressure index (ABPI) <0.90, or;

2. Drop in ABPI >0.15 after exercise, or;

3. Toe-brachial pressure index (TBPI) <0.70, and;

4. Duration of complaints > 2 weeks;

5. Scheduled for DSA with antegrade femoral puncture;

6. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Renal failure; serum creatinine > 130 µmol/l;

2. Inability to give informed consent, or;

3. Patient participation in another study.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	16-04-2012
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-04-2012
Soort:	Eerste indiening

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	NL3254
NTR-old	NTR3406
Ander register	METC AMC : 2011_268
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A