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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21387

Source
NTR

Brief title
IODIL

Health condition

Peripheral Arterial Disease
Critical Limb Ischemia
Intermittent Claudication

Sponsors and support

Primary sponsor: Academic Medical Center (AMC) Amsterdam
Source(s) of monetary or material Support: The study is financial supported partially by GE Healthcare.

Intervention

Outcome measures

Primary outcome

Confidence in diagnosing and treating arterial stenoses or occlusions.

Secondary outcome

Image quality scores.

Study description

Background summary

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.

Study objective

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

Study design

The patient gets the intervention with the assigned contrast and 2-3 days after the procedure, blood will be withdrawn to assess renal function.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

Intervention

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

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

2. Inability to give informed consent, or;

3. Patient participation in another study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-04-2012
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-04-2012
Application type:	First submission

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

Study results

Summary results
N/A