IOinated contrast DILution in digital subtraction angiography of the limb: a randomized controlled trial with three different concentrations of iodine

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To compare the confidence of the interventional radiologist in diagnosing and treating arterial stenoses and occlusions by digital subtraction angiography with contrast concentrations of 300, 240 and 140 mg iodine per ml. Also, we will compare the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON39902

Source
ToetsingOnline

Brief title
IODIL

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Peripheral arterial disease, vascular calcification of the limb

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: contrast dilution, digital subtraction angiography, iodinated contrast, peripheral arterial disease

Outcome measures

Primary outcome

- The confidence score (scale of 0 to 100) in diagnosing arterial stenosis or

occlusion during digital subtraction angiography.

- The confidence score (scale of 0 to 100) in treating arterial stenosis or

occlusion during digital subtraction angiography.

Secondary outcome

- Imaging quality score (four-point scale) during diagnosis and treatment of

arterial stenosis or occlusion during digital subtraction angiography.

Study description

Background summary

Peripheral arterial disease is a common manifestation of systemic atherosclerosis. Almost 10% has peripheral arterial disease on the age of 60 years, which can present as intermittent claudication or critical limb ischemia. The interventional radiologist can perform a digital subtraction angiography to treat stnoses or occlusions. This procedure uses iodinated contrast. In the acadimc medical center a contrast concentration of 300 mg of jodium per ml is used. This contrast is associated with complications, such as contrast induced nephropathy or allergic reactions. Research for alternative contrast media, such as carbon dioxide and gadolinium, do not give the desired results to replace the iodinated contrast. To decrease the risk for complications lowering the contrast concentration is another option. The only question is whether the imaging quality is adequate enough for proper diagnostics and treatment. Therfore we want to study what influences a lowered iodinated contrast concentration has on imaging quality compared to the

currently used concentration.

Study objective

To compare the confidence of the interventional radiologist in diagnosing and treating arterial stenoses and occlusions by digital subtraction angiography with contrast concentrations of 300, 240 and 140 mg iodine per ml. Also, we will compare the imaging quality at these different concentrations.

Study design

Prospective, three-armed, double-blind study that evaluates the imaging quality of three different iodinated contrast concentrations on digital subtraction angiography in patients with peripheral arterial disease.

Study burden and risks

The additional burden for the patient is the completion of the baseline questionnaire. The patient will be asked to return to the hospital two to three days after the angiography for withdrawal of blood, so it can be determined whether there is contrast-induced nephropathy. The risks of participation to this study is also limited. By allocating lower iodinated contrast concentrations, there is a chance that imaging quality is poor and the radiologist decides to switch to the standard concentration. If this happens, the patient is at risk that more contrast will be administered than would have been done if the patient was not part of this study. This additional exposure could lead to contrast-induced nephropathy and allergic reactions.

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

>18 years old
Diagnosis of peripheral arterial disease, defined as ankle-brachial pressure index (ABPI)<0.90, or drop in ABPI >0.15 after exercise, or toe-brachial pressure index <0.70.
Referred for digital subtraction angiography with antegrade femoral puncture
Duration of complaints > 2 weeks
Written informed consent

Exclusion criteria

Patient participation in an other study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-04-2012
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	08-11-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL37701.018.11