Diagnostic Imaging for Peripheral Arterial Disease: the DIPAD trial.

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Is the diagnostic imaging workup of patients with peripheral arterial disease performed initially with MR angiography cost-effective compared to the currently employed workup with duplex ultrasound or CT angiography?

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26004

Bron
Nationaal Trial Register

Verkorte titel
DIPAD trial

Aandoening

Peripheral arterial disease (PAD) is the expression of atherosclerosis in the lower limb distal to the aortic bifurcation, which is a major problem in the population of 55 years and older. The first manifestation of symptomatic PAD is usually intermittent claudication. In a minority of patients, the disease progresses to critical limb ischemia, i.e. rest pain and tissue necrosis. PAD was defined as symptoms of intermittent claudication and/ or critical ischemia with an ankle-brachial index < 0.90.

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcomes evaluated were quality of life and costs.

Toelichting onderzoek

Achtergrond van het onderzoek

Peripheral arterial disease (PAD) is the expression of atherosclerosis in the lower limb distal to the aortic bifurcation, which is a major problem in the population of 55 years and older. The first manifestation of symptomatic PAD is usually intermittent claudication. In a minority of patients, the disease progresses to critical limb ischemia, i.e. rest pain and tissue necrosis. If PAD is suspected on the basis of patient history and physical examination, ankle-brachial indices (ABI) are generally measured to document the severity of the disease.
Diagnostic imaging is performed when PAD becomes lifestyle limiting and a revascularization procedure is considered. Non-invasive imaging tests including Duplex ultrasound (DUS), computed tomographic angiography (CTA), and magnetic resonance angiography (MRA) are increasingly used for the initial evaluation of patients with PAD. DUS provides both anatomical and functional information about the arterial system and has been shown to be a reliable modality with fairly good sensitivity and specificity. DUS is, however, operator dependent and does not provide a precise roadmap for planning treatment. Both MRA and CTA are relatively new non-invasive vascular imaging tests used in the diagnostic workup of peripheral arterial disease. Both modalities provide three-dimensional images of the arterial system with high sensitivity and specificity.
Disadvantages of MRA include the higher investment cost for equipment, the small number of cases in whom the image is uninterpretable due to artifacts, and the fact that some patients are claustrofobic or have a contraindication for MR scanning. The main disadvantages of CTA are the use of radiation, the use of potentially nephrotoxic iodinated contrast media, vessel wall calcifications that affect image interpretation, and the time-consuming 3D reconstruction techniques. The question arises which imaging test is preferred in the diagnostic work-up of PAD.
To determine which non-invasive test is preferred as initial imaging test in clinical practise we need to take into account not only the diagnostic accuracy of each test, but also the related

effects of diagnostic imaging tests on treatment planning, functional improvement, quality of life, and costs. For this purpose we designed the Diagnostic Imaging of Peripheral Arterial Disease (DIPAD) randomized trial to compare outcomes following DUS, MRA, and CTA as the initial imaging test in the diagnostic workup of patients with peripheral arterial disease. Primary outcomes evaluated were quality of life and costs. Secondary outcomes evaluated were clinical utility and functional patient outcomes.

Doel van het onderzoek

Is the diagnostic imaging workup of patients with peripheral arterial disease performed initially with MR angiography cost-effective compared to the currently employed workup with duplex ultrasound or CT angiography?

Onderzoeksproduct en/of interventie

1. Magnetic resonance angiography: requires intravenous contrast material injection and duration of the examination is 30 minutes;

2. Duplex ultrasound: requires no intravenous contrast material injection and duration of the examination is variable;

3. Computed tomographic angiography:requires intravenous contrast material injection and duration of the examination is 10 minutes.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Men and women at least 18 years old with symptomatic PAD and an ankle-brachial index <0.90 who were referred from the Department of Vascular Surgery for a diagnostic imaging workup to evaluate the feasibility of a revascularization procedure were eligible for enrollment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients were excluded if they had contraindications for MR angiography (eg, pacemaker, cerebral vessel clipping, or claustrophobia) or CT angiography (eg, severe renal insuffiency or adverse reactions to iodinated contrast agent), or if they needed an acute intervention at the time of randomization.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2001
Aantal proefpersonen:	514
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	08-09-2005
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	NL160
NTR-old	NTR195
Ander register	: N/A
ISRCTN	ISRCTN2671851

Resultaten

Samenvatting resultaten

1. AJR Am J Roentgenol. 2008 May;190(5):1349-57;
2. Radiology. 2005 Sep;236(3):1094-1103;
3. J Vasc Surg. 2005 Feb;41(2):261-268.