# Diagnostic Imaging for Peripheral Arterial Disease: the DIPAD trial

Submission date	Recruitment status	Prospectively registered	
20/12/2005	No longer recruiting	[_] Protocol	
Registration date	Overall study status	Statistical analysis plan	
20/12/2005	Completed	[X] Results	
Last Edited 09/11/2022	<b>Condition category</b> Circulatory System	[] Individual participant data	

### Plain English summary of protocol

Not provided at time of registration

## **Contact information**

**Type(s)** Scientific

**Contact name** Dr R. Ouwendijk

#### **Contact details**

Department of Radiology Erasmus Medical Center Rotterdam P.O. Box 2040 Rotterdam Netherlands 3000 CA

r.ouwendijk@erasmusmc.nl

# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

**Secondary identifying numbers** Nil known

## Study information

**Scientific Title** Diagnostic Imaging for Peripheral Arterial Disease: the DIPAD trial

Acronym DIPAD trial

#### Study objectives

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

**Ethics approval required** Old ethics approval format

**Ethics approval(s)** Ethics approval received from the local medical ethics committee

**Study design** Multicentre, randomised, active controlled, parallel group trial

**Primary study design** Interventional

Secondary study design Randomised controlled trial

**Study setting(s)** Hospital

**Study type(s)** Diagnostic

Participant information sheet

#### Health condition(s) or problem(s) studied

Peripheral Arterial Disease (PAD)

#### Interventions

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

**Intervention Type** Other **Phase** Not Specified

#### Primary outcome measure

Primary outcomes evaluated were quality of life and costs.

#### Secondary outcome measures

Secondary outcomes evaluated were clinical utility and functional patient outcomes.

## Overall study start date

01/12/2001

## Completion date

01/10/2003

## Eligibility

#### Key inclusion criteria

- 1. Men and women at least 18 years old
- 2. Symptomatic Peripheral Arterial Disease (PAD)
- 3. An ankle-brachial index less than 0.90

4. Referred from the Department of Vascular Surgery for a diagnostic imaging workup to evaluate the feasibility of a revascularisation procedure

#### Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

Sex

Both

# **Target number of participants** 514

#### Key exclusion criteria

1. Contraindications for MR angiography (e.g., pacemaker, cerebral vessel clipping, or claustrophobia) or CT angiography (e.g., severe renal insufficiency or adverse reactions to iodinated contrast agent)

2. Need an acute intervention at time of randomisation

### Date of first enrolment

01/12/2001

# Date of final enrolment 01/10/2003

## Locations

**Countries of recruitment** Netherlands

**Study participating centre Department of Radiology** Rotterdam Netherlands 3000 CA

## Sponsor information

**Organisation** Erasmus Medical Centre (Netherlands)

**Sponsor details** Dr Molewaterplein 40/50 Rotterdam Netherlands 3000 CA

**Sponsor type** University/education

Website http://www.erasmusmc.nl/

ROR https://ror.org/018906e22

## Funder(s)

**Funder type** Research organisation

**Funder Name** The Netherlands Organization for Health Research and Development (ZonMw) (The Netherlands)

# **Results and Publications**

#### Publication and dissemination plan

Not provided at time of registration

#### Intention to publish date

#### Individual participant data (IPD) sharing plan

Not provided at time of registration

#### IPD sharing plan summary

Not provided at time of registration

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>		01/09/2005		Yes	No
<u>Results article</u>		01/08/2006		Yes	No