

Fluoroscopy with MRA fusion image guidance in endovascular iliac artery intervention

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21907

Source

NTR

Brief title

3DMR-ILIAC-ROADMAPPING

Health condition

Peripheral arterial disease of the iliac arteries.

Sponsors and support

Primary sponsor: None

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The amount of iodinated contrast agents used

Secondary outcome

- Technical success (yes/no)
- Procedure time (minutes)
- Dose Area Product (mGy*cm²)
- Registration of complication (free field)
- Total radiation time (minutes, seconds)
- Cost effectiveness

Study description

Study objective

The use of additional information provided by 3D fusion road-mapping software will reduce the amount of iodinated contrast agents used compared with endovascular iliac procedures without 3D fusion road-mapping guidance.

Study design

Data will be obtained from and directly after the intervention

Intervention

Patients are randomized to either the a standard of care PTA procedure or a PTA procedure guided by the 3D fusion road-mapping guidance.

Contacts

Public

St. Antonius Ziekenhuis (Vaatchirurgie)
S.G.H Heinen
Nieuwegein
The Netherlands
088-320 1925 (Secretariaat Heelkunde)

Scientific

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Eligibility criteria

Inclusion criteria

- Patient suffering from peripheral arterial disease with a stenosis or occlusion in the iliac arteries who will undergo a PTA procedure
- A diagnostic CE-MRA (<6 months)
- Written informed consent

Exclusion criteria

- Patient under the age of 18
- Patients with acute ischemic limbs
- Patients without written informed consent
- Pregnancy or breast-feeding

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Control: Active

Recruitment

NL	
Recruitment status:	Other
Start date (anticipated):	08-10-2015
Enrollment:	106
Type:	Unknown

Ethics review

Not applicable

Application type:

Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 44927

Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4906
NTR-old	NTR5008
CCMO	NL47680.068.14
OMON	NL-OMON44927

Study results