FLUOROSCOPY WITH 3D MRA FUSION GUIDANCE IN ENDOVASCULAR ILIAC ARTERY INTERVENTIONS

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The objective of this prospectieve comparing multicenter study is to analyze the possible benifits on iodinated contrast, fluoroscopy time and irradiation dose by using the 3D fusion roadmap in iliac endovascular interventions .

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

Summary

ID

NL-OMON44927

Source
ToetsingOnline

Brief title
3DMR-iliac-roadmap

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
intermittent claudication, peripheral arterial disease

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cone Beam Computed Tomography, fusion navigation, percutaneous transluminal angioplasty, Peripheral arterial disease

Outcome measures

Primary outcome

- The amount of iodinated contrast agent used during the procedure (ml)

Secondary outcome

- Total fluoroscopy time (in minutes en seconds)

- Total procedure time (in minutes)

- Total radiation exposure i.e. Dose area product (mGy*cm^2)

- Technical success of the procedure (Yes versus No).

- Registration of possible complications (Free text).

- Costeffectiveness of the fusion navigation software

Study description

Background summary

Fusion navigation is a new technique used during endovascular interventions . Both, the Acadmisch Hospital Maastricht (AZM) and the St. Antonius Hospital in Nieuwegein have the required state of the art equipment and software available to perform those fusion guided interventions which are already used in practice. From several publications it is known that the use of 3D fusion roadmapping leads to a significant reduction used during endovascular procedure. Since 2012 the AZM is performing studies on the feasibility of the 3D fusion roadmap when treating complex aneurysms (METC number 12-4-125) . 3D fusion roadmapping for peripheral vessels such as the iliac vessels has not been randomized investigated.

To investigate the potentiel benefits of the fusion 3D roadmap, this randomized multi-center study initiated which will compare iliac endovascular interventions with and without fusion 3D roadmap guidance. The group without the 3D fusion roadmap is treated the conventional way with fluoroscopy imaging.

In the group with the 3D fusion roadmap, the earlier diagnostic MRA of the pelvic and leg arteries is linked to the fluoroscopy images made during the procedure. The obtained 3D fusion roadmap is available next to the normal fluoroscopy images.

The data related to iodinated contrast agent used, irradiation dose (Dose Area Product), fluoroscopy time , total procedure time, and technical success is standardized, collected and both groups are compared with each other. Possible complications will be registered . Patients are asked to fill out an informed consent.

Study objective

The objective of this prospectieve comparing multicenter study is to analyze the possible benifits on iodinated contrast, fluoroscopy time and irradiation dose by using the 3D fusion roadmap in iliac endovascular interventions .

Study design

This studie is a prospective randomized comparing multi-center studie. All patients that meet the inclusion criteria may be asked to participate in our study. After filling out informed consent, patients will be randomized in the group with or without 3D fusion roadmap technique. The group without 3D fusion roadmap undergoes the conventional treatment with fluoroscopy imaging, as is the standard of care method. Next to conventional imaging, when performing the intervention in th group with the 3D fusion roadmapping additional imaging is used. Theretofore, before starting the endovascular procedure patients undergo a contrast-free CBCT which is linked to the diagnostic MRA. The created MRA fusion roadmap is used during the procedure and gives additional information.

Intervention

All included patients will be randomized into 2 groups. The first group is treated conform the standard of care PTA procedures. The other group undergoes a PTA procedure with guidance of the 3D MR fusion roadmap.

Study burden and risks

It is known from resent publications that the use of 3D fusion roadmapping during iliac endovasculair procedures leads to a significant reduction of the amount of iodinated contrast used. The extra dose due to CBCT is comparable with 1.5 times the annual background dose in the Netherlands. The health risk related to the dose obtained can be categorized as very low.

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

* All Patients which are suffering from Peripheral Arterial Disease (PAD) and need endovascular treatement of the iliac arteries.
* An MRA examination, no older than six months and artefact free.
* Signed informed consent

Exclusion criteria

* Patients under 18.
* Mental disability that hinders the ability to understand and comply with the informed consent.
* Patients who need acute treatment

* Pregnancy or breast-feeding
* Patients without MRA because of contra-indications suchs as claustrophobia, pacemaker or gadolinium allergy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-04-2016
Enrollment:	106
Type:	Actual

Medical products/devices used

Generic name:	Philips MR-CT Roadmap
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	10-06-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	11-04-2018

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21907
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL47680.068.14
OMON	NL-OMON21907