First-in-man use of DMUA/HIFU therapy for the treatment of atherosclerotic plaques in the femoral artery

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To investigate the feasibility and safety of the DMUA-HIFU system for treatment of atherosclerotic plaques.

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

Summary

ID

NL-OMON54816

Source
ToetsingOnline

Brief title
HIFU-study

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerosis, plaque

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: bedrijf (International Cardio Corporation),International cardio corporation

Intervention

Keyword: atherosclerotic plaque, High intensity focused ultrasound, peripheral arterial disease, treatment

Outcome measures

Primary outcome

To investigate the safety of DMUA / HIFU therapy for the treatment of symptomatic atherosclerotic plaques of the femoral artery, the thirty-day major complication rate will be used as primary endpoint. The 30-day procedure related major complication rate is a composite safety endpoint, based on previously validated safety endpoints for symptomatic peripheral arterial disease. It consists of the 30-day major adverse limb event (MALE) rate, which is defined as any complication that requires endovascular revascularization, open revascularization, or amputation in the target limb. Secondly, it consists of the 30-day mortality rate.

Secondary outcome

See studyprotocol chapter 7.1.1., 7.1.2., 7.2.

Technical

To investigate the feasibility of the DMUA / HIFU therapy for the treatment of symptomatic atherosclerotic plaques of the femoral artery, technical parameters defined as technical success (protocol 7.1.2.) will be used.

Magnetic resonance imaging (MRI) parameters

To investigate changes in morphology of the symptomatic atherosclerotic plaque

and the vascular lumen, the femoral artery will be imaged before, 1 day after and 30 days after treatment (protocol 7.2).

Echo-duplex parameters

To investigate vascular patency, changes in duplex imaging of the common femoral artery before and during follow-up will be measured (protocol 7.2)

Clinical parameters

To investigate changes in functional performance of the patient, the 6-minute walking test will be used to measure the walking distance before the procedure and 30 days after the procedure (protocol 7.2).

To investigate changes in vascular patency, the ankle-brachial index will be measured before the procedure during follow-up (protocol 7.2).

Secondary safety endpoint

To investigate the 30-day and 90-day overall complication rate, consisting of both minor (protocol 7.1.2.) and major complications (protocol 7.1.1.) that might occur within 30 and 90 days of the procedure

Quality of life parameters

To investigate changes in the patient*s quality of life, the patient will be asked to fill in a Dutch *quality of life questionnaire*, specifically designed for patients with peripheral arterial disease, at baseline visit and during

follow-up (appendix B)

Study description

Background summary

Current treatment of lower extremity peripheral arterial disease consists of risk factor modification, exercise therapy and pharmacological treatment initially, but intervention is frequently needed when patients are significantly disabled. Interventional treatment is invasive, either surgical or percutaneous. This study investigates a new non-invasive technique that uses high intensity focused ultrasound to treat atherosclerotic arterial disease

Study objective

To investigate the feasibility and safety of the DMUA-HIFU system for treatment of atherosclerotic plaques.

Study design

Monocentre first-in-man non-randomized interventional pilot study (n=15).

Intervention

All patients will be treated with the dual-mode ultrasound array (DMUA) system to deliver imaging-guided high-intensity focused ultrasound (HIFU) to the atherosclerotic plaque.

Study burden and risks

Preclinical studies in healthy and diseased animals have demonstrated that the use of the DMUA/HIFU therapy is safe. However, there is no previous experience with this therapy in humans. With regard to the experience of the preclinical studies, the risk of major adverse events like thrombotic events is considered to be very low. The treatment is expected to be painless, but local skin irritation may occur. If proven effective and safe, the DMUA/HIFU therapy can represent a fast, simple and painless treatment that can be performed at the outpatient clinic as an alternative to invasive surgical intervention.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Maximal patient age is 85 years 2. Patient is diagnosed with symptomatic peripheral arterial disease (ankle brachial index <0,9), with focal localisation proximally in the femoral artery 3. Patient has a (non-stented, non-restenotic) target lesion with a 50-90% occlusion or symptoms with a total lesion length of <= 40mm. 4. Presence of CTA-imaging of the target lesion in the patient*s medical file at baseline (<2 year old), from which the max depth (<35mm) of the femoral arterial posterior wall from the skin surface is measured and the degree of plaque calcification can be measured. 5. The target vessel and/or lesion must be visible on ultrasound-imaging of the DMUA/HIFU-system.

Exclusion criteria

1. Patient is diagnosed with early onset peripheral arterial disease. 2. The maximum distance from the skin surface to the dorsal vessel wall exceeds 35 mm

3. The research team is unable to locate target vessel/lesion with ultrasound-imaging of the DMUA/HIFU-system 4. Volume of calcified areas in the plaque more than 80% of the culprit lesion, and/or distribution of calcification in the culprit lesion which the research team considers not suitable for HIFU-treatment after preprocedural assessment of existing CTA-images. 5. Plaque that in the opinion of the research team is unsuitable for HIFU-treatment after baseline screening of patients. For example, unstable plaque (e.g. thin fibrous cap, or intraplaque haemorrhage). 6. Presence of any anatomical structures located near the focus of the HIFU beam, that in the opinion of the study team would interfere with safe delivery of the therapy (e.g. nerves, bone, extensive scar tissue). 7. History of prior femoral artery stenting at the contemplated target location. 8. Recent (<6 months) cardiovascular event (myocardial infarction, unstable angina pectoris, TIA/CVA) or major surgery. 9. Contraindication for antiplatelet therapy (e.g. high risk of bleeding, severe renal insufficiency) 10. Any serious medical condition or any other (medical, physical, anatomical) considerations, which in the opinion of the study team may adversely affect the safety of the participant in the study 11. Individual has any contraindications for any of the study investigations (e.g. claustrophobia for MRI). 12. Individual has a known, unresolved history of substance abuse or alcohol dependency, lacks the ability to comprehend or follow instructions or would be unlikely or unable to comply with the study protocol. 13. Individual is currently enrolled in another investigational or device trial. 14. Individual is pregnant, nursing or planning to be pregnant.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-07-2019
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Dual mode ultrasound array (DMUA)/ High intensity focused ultrasound (HIFU)
Registration:	No

Ethics review

Approved WMO Date:	25-02-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	18-04-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-07-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-01-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	10-07-2023
Application type:	Amendment
Review commission:	METC NedMec

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	NL66436.041.18