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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21240

Source
NTR

Brief title
HIFU-study

Health condition

Study population:
Patients diagnosed with symptomatic atherosclerotic plaques of the common femoral and/or proximal superficial artery.

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: Subsidising party: International Cardio Corporation

Intervention

Outcome measures

Primary outcome

30-day major complication rate, which is a composite endpoint that includes 30-day major adverse limb event rate and 30-day mortality.rate

Secondary outcome

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 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.

Echo-duplex parameters
To investigate vascular patency, changes in duplex imaging of the common femoral artery before and during follow-up will be
measured.

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

Secondary safety endpoint
To investigate the 30-day and 90-day overall complication rate, consisting of both minor and major complications
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.

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 endovascular. 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

Baseline, day of procedure, follow-up: +1d, +7d, +14d, +21d, +30d, +90d

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.

Contacts

Public
University Medical Center Utrecht
Fons Slieker

+31638820192
Scientific
University Medical Center Utrecht
Fons Slieker

+31638820192

Eligibility criteria

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 30% 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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	25-02-2019
Enrollment:	15
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	06-03-2019
Application type:	First submission

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
NTR-new	NL7564
Other	METC Utrecht : 18-680/H-D

Study results