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

Gepubliceerd: 06-03-2019 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21240

Bron
NTR

Verkorte titel
HIFU-study

Aandoening

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

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: Subsidising party: International Cardio Corporation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	25-02-2019
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	06-03-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7564
Ander register	METC Utrecht : 18-680/H-D

Resultaten