Photoacoustic imaging of atherosclerotic plaques

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The aim of this study is to investigate the feasibility of atherosclerotic plaque imaging using multispectral photoacoustic imaging.

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

Summary

ID

NL-OMON45668

Source
ToetsingOnline

Brief title
Photoacoustic imaging of atherosclerotic plaques

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Carotid artery stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Technische Universiteit Eindhoven Faculteit Biomedische Technologie
Source(s) of monetary or material Support: Europese Unie EU H2020 (C-VENT Project)

Intervention

Keyword: carotid artery, photoacoustic imaging, ultrasound, vulnerable plaque

Outcome measures

Primary outcome

The acoustic (i.e., echographic) and photoacoustic images will be analyzed to determine the ability of distinguishing between different plaque components (intraplaque hemorrhage, lipid pool, vessel wall), examine penetration depth, resolution, and contrast.

Secondary outcome

nvt

Study description

Background summary

Stroke is a major cause of death and disability worldwide. Stenotic carotid arteries can lead to stroke if the cause of the stenosis is a vulnerable atherosclerotic plaque. Recent studies reveal that if a patient has a plaque in the carotid artery it is highly probable that he/she will develop plaques in other superficial arteries like the femoral artery. Currently, duplex ultrasound is used to determine the grade of stenosis and is the main criterion for intervention (endarterectomy) planning. However, the stability, or instability of the plaque cannot be determined non-invasively. Photoacoustics is a novel, non-invasive imaging modality that uses pulsed laser light to generate laser induced ultrasound in the absorbing region of the tissue. Photoacoustic imaging provides optical contrast of biological tissue chromophores with an acoustic resolution and imaging depth, which is promising for visualization of plaque composition. The advantage of photoacoustics is the use of multiple wavelengths, since different tissues respond differently to different wavelengths. Hence, non-invasive, in vivo, morphology assessment is a future application of this new modality that would improve diagnosis and clinical decision making. The drawback is the limited penetration depth of the laser light and the signals generated by surrounding tissue.
A new, integrated photoacoustic device has been developed that meets all safety requirements and has an improved penetration depth, suitable for imaging of carotid arteries with the aim to distinguish between plaques with different morphology.

Study objective

The aim of this study is to investigate the feasibility of atherosclerotic plaque imaging using multispectral photoacoustic imaging.

Study design

This is a pilot study where 60 patients with a plaque in one of the carotids, scheduled for an endarterectomy procedure, will be included. Each subject will get a multi-wavelength photoacoustic examination of the carotid plaque. In one group (N = 30), photoacoustic imaging will be performed noninvasively at the TU/e laser lab, which is compliant with laser safety standards, to verify non-invasive, multi-angle, multi-wavelength photoacoustic imaging (Study A). In the second group (N = 30), photoacoustic imaging will be performed pre- and per-operatively (Study B) prior to plaque removal. Here, to ensure a 100% (laser) safe environment, all acquisitions will be performed in the operating theatre. The latter group will be subjected to additional Magnetic Resonance Imaging for validation.

Study burden and risks

For this study, the subject undergoes a regular 2D echography and additional non-invasive photoacoustic imaging. In study A, the patients will be requested to visit the PULS/e lab at the Eindhoven University of Technology for multi-wavelength photoacoustic imaging. The total exam will take 30 minutes of time. In study B, patients will be imaged during the endarterectomy procedure at CZE. First, photoacoustic images are acquired in the neck, prior to incision. The PA acquisition will be repeated after incision and exposure of the carotid bifurcation, before the surgeon will remove the plaque. Prior to the intervention, a sub-group of patients will be asked to visit the hospital for additional MR imaging.
The test subjects will not benefit from this examination. However, this pilot study will clarify whether the use of photoacoustic imaging of carotid arteries is feasible. It is expected that there are no risks or adverse outcomes for the subjects. A cost-effective device to identify plaque stability in patients to prevent stroke and reduce overtreatment will benefit the future population by reducing health care costs and risks involved.

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

In order to be eligible to participate in this study, a subject must be an adult that is fully competent to give informed consent that has been under surveillance for a plaque in one of the carotid arteries with a stenosis grade between 70 and 99% (based on prior Duplex US examination in the vascular lab) In case of study A, the subject should physically be able to be seated in a chair without moving for 10 to 20 minutes.

Exclusion criteria

Minors or incapacitated adults will not be included in the study. Subjects that do not want to participate will also not be included.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-02-2019
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	02-10-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL61451.100.17