Vector Flow Imaging in healthy vessels

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Primary objective:To evaluate the performance of bST and echoPIV in quantifying spatiotemporal blood flow velocity profiles in the CA and SFA of healthy volunteers in comparison to 4D flow MRI.Secondary objective:- To determine the correlation of...

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

Summary

ID

NL-OMON53908

Source
ToetsingOnline

Brief title
VFI in healthy vessels

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
carotid or superficial femoral artery stenosis; narrowing of the neck or upper leg artery

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Rijnstate Vriendenfonds bijdrage

Intervention

Keyword: - (contrast-enhanced) ultrafast ultrasound, - Carotid artery, - Supferficial femoral artery, - Vector Flow Imaging

Outcome measures

Primary outcome

Velocity vector data derived from bST, echoPIV and 4D flow MRI examinations at the CA and SFA will be used to calculate and visualize the spatiotemporal blood flow velocity profiles to assess the performance of the two VFI techniques compared to 4D flow MRI.

Secondary outcome

- Velocity vector data derived from bST and echoPIV at the CA and SFA will be used to calculate and visualize the spatiotemporal blood flow velocity profiles to assess the correlation between both VFI techniques.
- Velocity vector data obtained with the bST, echoPIV and 4D flow MRI measurements at the CA and SFA will be used to calculate blood flow derived parameters, such as vector complexity, vorticity and WSS. These parameters will be compared between the different techniques and 4D flow MRI.
- Spatiotemporal blood flow velocity profiles and blood flow derived parameters obtained at the CA and SFA using bST, echoPIV and 4D flow MRI will be compared between young and older healthy volunteers (group 1 and group 2).
- Spatiotemporal blood flow velocity profiles derived from the bST data obtained at the CA by observer 1 and observer 2 will be used to assess the inter-observer variation.
- Spatiotemporal blood flow velocity profiles derived from the bST data obtained two times at the CA by observer 1 will be used to assess the intra-observer variation.

Study description

Background summary

There is a wealth of evidence implicating the important role of blood flow throughout all stages of the process of atherogenesis. Two locations along the vascular tree at which atherosclerotic plaques are typically found are the carotid artery (CA) and the superficial femoral artery (SFA). Nowadays, ultrasound is the technique of choice for assessing the vascular condition in the CA and SFA. However, clinically used ultrasound techniques show a large variability in estimating the blood flow velocity, due to multiple limitations. With the advent of ultrafast ultrasound imaging, (almost) all elements of the transducer can be activated simultaneously. These so-called plane wave acquisition acquires thousands of images per second and makes continuous tracking of blood flow velocities in all directions in the field of view possible. This high-frame-rate acquisition opened up new possibilities for blood flow imaging at the CA and SFA, such as blood Speckle Tracking (bST) and ultrasound Particle Image Velocimetry (echoPIV). Both these vector flow imaging (VFI) techniques enable the quantification of 2D blood flow velocity profiles, where bST uses no contrast agents compared to echoPIV. Beside these novel ultrasound based techniques, 4D Phase Contrast Magnetic Resonance Imaging (4D flow MRI) enables a non-invasive quantification of the 4D blood flow velocity profiles (3D + time) and can be used as reference standard for blood flow assessments in-vivo. We therefore aim to evaluate the performance of both VFI techniques in comparison to 4D flow MRI measurements in the CA and SFA of healthy volunteers.

Study objective

Primary objective:
To evaluate the performance of bST and echoPIV in quantifying spatiotemporal blood flow velocity profiles in the CA and SFA of healthy volunteers in comparison to 4D flow MRI.

Secondary objective:
- To determine the correlation of spatiotemporal blood flow velocity profiles obtained with bST and echoPIV;
- To compute flow-derived parameters, such as vector complexity, vorticity and WSS, from the spatiotemporal blood flow velocity profiles and determine the correlation between all three techniques (bST, echoPIV and 4D flow MRI);
- To compare spatiotemporal blood flow profiles and flow-derived parameters between young and old healthy volunteers;
- To determine the intra- and inter-observer variability (i.e. repeatability and reproducibility, respectively) of bST in the CA.

Study design

Prospective, observational, feasibility study in a total of twenty healthy volunteers.

Study burden and risks

The burden for volunteers related to this study consists of a visit to the hospital. During this visit the bST, echoPIV, and 4D flow MRI measurements will be performed. The bST and echoPIV measurements will be performed using a research ultrasound machine that is not approved for clinical use. All required tests were performed to ensure a safe use of the machine. Moreover, ultrasound contrast agents will be intravenously injected that have a small risk of adverse events (<0.01%). At last, 4D flow MRI scans will be performed, which might be unpleasant because of the small tube and loud noise.

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

- Healthy male or female, without cardiovascular and pulmonary medical history and without the use of medication for cardiovascular risk factors.
- Age between 20-30 year or 65-75 years old
- Willingness to undergo a 4D flow MRI scan and US examinations
- Informed consent form understood and signed, and agrees to the hospital visit.

Exclusion criteria

- Hypersensitivity to the active substance(s) of any of the excipients in Sonovue.
- Pregnancy
- MRI exclusion criteria (such as presence of pacemaker, cerebral vascular clips, claustrophobia).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-11-2022
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Vantage 256
Registration:	No

Ethics review

Approved WMO Date:	31-03-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-10-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-01-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL80478.091.22

Study results

Date completed:	18-03-2023
Actual enrolment:	20