Vasa studie.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26282

Source
NTR

Brief title
VASA

Health condition

Patient from the outpatient clinic of Cardiology and Vascular Medicine with hypertension, diabetes mellitus, hypercholesterolemia, smoking, and/or a family history of cardiovascular disease

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Erasmus MC

Intervention

Outcome measures

Primary outcome

1. A quantification method for vasa vasorum imaging using contrast-enhanced ultrasound of the carotid arteries will be developed, using physical ultrasound parameters;

2. The vessel wall thickness (intima-media thickness) and vasa vasorum will be evaluated in patients with hypertension, diabetes mellitus, hypercholesterolemia, smoking, and/or a family

history of cardiovascular disease to assess the incidence and prevalence of an increased density of the vasa vasorum network;

3. A follow-up study will be performed to evaluate a relation between ultrasound parameters and prognosis.

Secondary outcome

1. Side-effects will be registered;

2. Image quality and interpretability will be evaluated.

Other study parameters:

1. Demographics, gender, age, body-mass index;

2. Cardiovascular risk profile (SCORE).

Study description

Background summary

Atherosclerosis is a progressive chronic inflammatory disease that may be complicated by cardiovascular events. Early identification of atherosclerosis is important to start treatment (for example with statins) at an early point in the disease cycle. The formation of microvessels within the vessel wall and plaque could be used as an early sign of atherosclerosis and plaque vulnerability. Barger et al initially described the possible role of vasa vasorum, the microvessels that nourish the vessel wall, in the development of atherosclerosis. Recently, several non-invasive imaging techniques have become available for detecting vasa vasorum. Contrast-enhanced ultrasound imaging of the carotid arteries is perhaps the most promising imaging modality, because of its high spatial and temporal resolution. Contrast-enhanced ultrasound is safe, and the repeatability of recording, and cost provide an incentive to develop approaches using this modality. The broad long-term goal of the proposed effort is to develop a widely available, simple, cost-effective technology to screen populations considered to be at risk of future cardiovascular events. Another broad goal of the proposal is to investigate the role of increased neovascularization (vasa vasorum) within the arterial wall. Through the development and validation of a non-invasive, ultrasound-based imaging, we will provide a method for the early detection of atherosclerosis in individuals considered to be at risk for a future cardiovascular event.

Study objective

Primary Objectives:

1. A quantification method for vasa vasorum imaging using contrast-enhanced ultrasound of the carotid arteries will be developed, using physical ultrasound parameters;

2. The vessel wall thickness (intima-media thickness) and vasa vasorum will be evaluated in patients with hypertension, diabetes mellitus, hypercholesterolemia, smoking, and/or a family history of cardiovascular disease to assess the incidence and prevalence of an increased density of the vasa vasorum network;

3. A follow-up study will be performed to evaluate a relation between ultrasound parameters and prognosis.

Secondary Objective(s):

1. Side-effects will be registered;

2. Image quality and interpretability will be evaluated.

Other study parameters:

1. Demographics, gender, age, body-mass index;

2. Cardiovascular risk profile (SCORE).

Study design

Each year differences between patients with and without vasa vasorum will be anallyzed.

Intervention

This is an observational study, no interventions are planned.

Contacts

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Eligibility criteria

Inclusion criteria

1. >18 years of age;

2. Presence of cardiac risk factors.

Exclusion criteria

1. Unstable clinical symptoms;

2. Contraindications for contrast-enhanced ultrasound.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-03-2010
Enrollment:	200
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL2122
NTR-old	NTR2239
Other	METC Erasmus MC : 2009-381
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A