ARTErial calcifications of the Media and Intima in SMART

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To answer the following research questions: 1. Do intimal arterial calcification and medial arterial calcification in the lower extremity arteries increase the occurrence of cardiovascular disease in people with a high risk of cardiovascular disease...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON44722

Source
ToetsingOnline

Brief title
ARTEMIS

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
cardiovascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Nederlandse Hartstichting Dr. Dekkerbeurs (2013T120;JW Beulens)

Intervention

Keyword: Arterial calcification, Cardiovascular disease

Outcome measures

Primary outcome

Endpoints research question 1: Cardiovascular disease events: coronary heart disease, stroke, peripheral artery disease, heart failure and vascular complications of diabetes.

Endpoints research question 2: Intimal arterial calcification and medial arterial calcification in the lower extremity arteries.

Secondary outcome

Not applicable

Study description

Background summary

Intimal and medial arterial calcification are two types of arterial calcification that can occur independently and are distinct in their morphology. However, not much is known about the differences in their determinants and respective clinical consequences.

Study objective

To answer the following research questions:
1. Do intimal arterial calcification and medial arterial calcification in the lower extremity arteries increase the occurrence of cardiovascular disease in people with a high risk of cardiovascular disease, and do their relationships with cardiovascular disease differ?
2. What are the risk factors for intimal arterial calcification and medial arterial calcification in the lower extremity arteries in people with a high risk of cardiovascular disease? To what extent do they differ or overlap?

Study design

SMART: This study is an observational cohort study nested within the SMART (Secondary Manifestations of ARTerial disease) cohort. The SMART study is an ongoing prospective cohort study in which all included patients undergo extensive baseline screening and receive a follow-up questionnaire every 6 months. ARTEMIS participants will undergo CT scanning of the lower extremity to assess the presence of medial and intimal arterial calcification.

DCS: The Hoorn Diabetes Care System (DCS) cohort consists of persons with type 2 diabetes in regular care from the West-Friesland region. All type 2 diabetes patients in this region of the Netherlands are referred to the Diabetes Care System for their treatment. Enrolment of the cohort started in 1998. Currently, this prospective dynamic cohort holds 12,733 persons with type 2 diabetes with at least one measurement. Annually, all living patients visit the DCS for the annual monitoring of their diabetes care, currently over 8,000 patients. During this visit HbA1c, fasting glucose, blood lipids, renal function, ECG, blood pressure, anthropometry, medication use, diabetes complications and questionnaires are collected. Part of the patients have provided consent to use these data for research and these patients can be included in this study. If DCS participants consent to participate to ARTEMIS, an extra visit for the ankle brachial index, blood sampling and CT scan of the legs and coronary arteries (calcium score) will be scheduled.

Study burden and risks

SMART: CT scanning of the legs will be performed without the use of contrast fluid. Scanning will take approximately 5 minutes in total (actual CT scan 3 seconds) and the burden of the procedure is low. The radiation dose will be <1mSv, with low associated risk.
No extra site visit will be needed, as the CT scan will be planned at time of the SMART or SMART2 visit.

DCS: CT scanning of the legs and the heart will be performed without the use of contrast fluid. Scanning will take approximately 15 minutes (actual scan 50 seconds). The radiation dose will be between 1.6 and 2.0 mS, with low associated risk. An additional visit will be necessary to perform the CT scan at WestFries Gasthuis.

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

Subject fulfils the general SMART/DCS inclusion criteria and agrees to be included in the SMART / DCS cohort.
Subject agrees to undergo lower extremity CT scanning during the SMART or SMART2 visit. For the DCS cohort, an additional visit will be necessary to perform the CT scan of the legs and heart at WestFries Gasthuis.

Exclusion criteria

Subject underwent bilateral lower extremity amputation
Subject is pregnant
Subject is a participant in the SMART-Medea study

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-03-2015
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO Date:	22-10-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-03-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-04-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL47647.041.14