Optimising Risk Assessment with CT-angiography or Calcium Score in patients at high risk for a cardiovascular event.

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1.To determine whether there is additional value of performing CAC score, CTCA and total aorta calcification (TAC) burden as compared to traditional risk factors in the risk stratification in patients at high cardiovascular risk in predicting any…

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

Summary

ID

NL-OMON54796

Source
ToetsingOnline

Brief title
SMART-ORACLE

Condition

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

Synonym
Atherosclerosis, vascular diseases

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Calcium Score, Cardiovascular Event, CT-angiography, Prediction

Outcome measures

Primary outcome

Combined endpoint of cardiovascular events (cardiovascular death, non-fatal myocardial infarction and non-fatal ischemic stroke)

Secondary outcome

-Coronary artery intervention (PCI, CABG)

-Carotid desobstruction or stenting

-Non-fatal rupture, stenting or operation of an abdominal aorta aneurysm ,

-Amputation, PTA (percutaneous transluminal angioplastic) or stenting due to peripheral artery disease

-All cause mortality

Study description

Background summary

After having had a first cardiovascular event, there is a considerable risk of developing a subsequent event. Only recently, a risk predictionmodel was developed for this group of patients. Imaging techniques such as the coronary calcium score and computed tomography angiography could be able to add accuracy to this model. When better risk stratification is possible, patients at the highest risk can be monitored and treated more intensively. When imaging techniques prove to be useful in the risk prediction model, a trial should be performed evaluating the effects on outcome measures such as morbidity and mortality

Study objective

1.To determine whether there is additional value of performing CAC score, CTCA and total aorta calcification (TAC) burden as compared to traditional risk

factors in the risk stratification in patients at high cardiovascular risk in predicting any cardiovascular event.
2.To estimate the additional value of CTCA and CAC score on top of traditional risk factors in predicting cardiac events in patients at high risk.
3.To determine the value of soft plaque burden in the carotid and coronary arteries in predicting vascular events in patients at high cardiovascular risk.

Study design

An observational cohort study, imbedded in the SMART study

Study burden and risks

Patients participating in the study will undergo a CT-scan with contrast of the neck till abdomen, performing both coronary/total aortic calcium scores as well as CT-angiography of the coronary vessels and carotid arteries. This CT-scan will be imbedded in the program of the original SMART (2) measurements and will take approximately 30 minutes. Both radiation and contrast will be used in performing the CT-scan, with a maximum of 8mSv of radiation and low-volume contrast. Patients with renal dysfunction will be either excluded from the study or will receive hydration (depending on their eGFR) to minimize the risk of contrast nephropathy. Adequate medication will be present in case of an allergic reaction to contrast.

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

Patients participating in either SMART or SMART-2 and who have one of the following:
- History of cardiovascular event (Coronary artery disease, Cerebrovascular disease, including TIA or Peripheral artery disease, including aortic aneurysm)
- Diabetes Mellitus type 2
- Hypertension

Exclusion criteria

-Known renal failure (defined as eGFR <30 ml/min/1.73 m2 estimated by MDRD formula)
-Previous allergic reaction to contrast, making medical intervention necessary
-Other contra-indication for CT-scanning
-Previous exposure to radiation for scientific purposes without advantage for the patient

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-06-2012
Enrollment:	1500
Type:	Actual

Medical products/devices used

Generic name:	CT-scan
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-01-2012
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	14-11-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-01-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-02-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-05-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	03-02-2023

Application type:	Amendment
Review commission:	METC NedMec

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	NL36828.041.11