Prediction of AtheRosclerotic plaque burden progression with SEquential Coronary CT-angiography and biomarkers (PARSEC-NET).

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To predict atherosclerotic plaque progression, and thus cardiovascular risk, by combining plaque quantification on CCTA with semi-automated software combined with biochemical characteristics, as defined by measuring biomarkers involved in...

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

Summary

ID

NL-OMON41961

Source
ToetsingOnline

Brief title
- Acroniem: PARSEC-NET.

Condition

- Coronary artery disorders

Synonym
atherosclerotic heart disease, Coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Atherosclerosis, Coronary artery disease, Disease progression

Outcome measures

Primary outcome

• Plaque progression as determined by sequential semi-automated plaque

quantification on CCTA.

• Whether plaque progression can be predicted by combining plaque

quantification with biomarkers involved in atherothrombosis.

Secondary outcome

Not applicable.

Study description

Background summary

The disruption of an atherosclerotic plaque and intraluminal thrombus formation are the pathological hallmarks of an acute coronary syndrome (ACS) in patients with coronary artery disease (CAD), which subsequently can lead to cardiac death. Despite advancements, identifying these patients at risk for an acute cardiovascular event remains an important clinical challenge3. Cardiac computed tomography angiography (CCTA) is currently a well-implemented diagnostic imaging modality in patients with stable chest pain. Besides conventional CT-reading (coronary calcium score, luminal stenosis severity, and extent of CAD), CCTA is also capable to identify several morphologic and geometric characteristics of atherosclerotic plaques. Recently we showed that the use of semi-automated plaque quantification algorithm identified parameters predictive for ACS on top of clinical risk profiling and conventional CT-reading. On the other hand, several atherotrombosis biomarkers, like high-sensitivity cardiac troponins, are described in literature as related to CAD and cardiovascular events which are an important part of risk stratification strategies. Prospective data with sequential analysis of atherosclerotic plaque progression by semi-automated software combined with biomarkers involved in

atherothrombosis are currently lacking.

Study objective

To predict atherosclerotic plaque progression, and thus cardiovascular risk, by combining plaque quantification on CCTA with semi-automated software combined with biochemical characteristics, as defined by measuring biomarkers involved in atherothrombosis.

Study design

Prospective, single-center cohort, feasibility study with sequential coronary CCTA for the assesment of plaque progression combined with the measurement of different biomarkers.
CCTA and samples of venous blood will be derived at baseline and 1-year after given informed consent. The semiautomated plaque quantification software of Siemens is going to be used to report the morphologic and geometric coronary plaque characteristics and to measure plaque progression.

Study burden and risks

The risks associated with participation are the occurrence of a hematoma due to blood sampling at the site of venipuncture (arm) and the radiation exposure - baseline and 1-year after given informed consent. Within the proposed study, only the follow-up CCTA is derived as an addition wherefore extra radiation exposure. But with recent developments in image acquisition and reconstruction technologies, nowadays CCTA is performed with relatively low radiation exposure. Meanwhile, the benefit of a second CCTA is that plaque progression can be determined and that we gain additive diagnostic information per patient and that in cases of peculiarity measures can be taken like referral to a medical specialist. Important is the fact that due to deriving serial CCTA and atherothrombosis biomarkers new insights on coronary plaque progression can be obtained since research on this is lacking.

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 with a recent history of (a)typical chest pain, who underwent a coronary Calcium score scan as well as coronary CT-angiography.
- At least 2 coronary segments with atherosclerotic plaques, as defined by coronary CT-angiography.

Exclusion criteria

- Unstable angina.
- Renal insufficiency: calculated estimated glomerular filtration rate <45mL/min.
- Iodine allergy.
- Pregnancy.
- Patients which are currently on oral vitamin K antagonists and using selective anticoagulants.
- Known history of atrial fibrillation.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-03-2015
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	25-08-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-02-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-02-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
Other	02394262
CCMO	NL49261.068.14