MYOcardial ischemia detection by circulating bioMARKERs: * the MYOMARKER-study*

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To analyse the diagnostic and prognostic value of plasma EV protein/miRNA and gene expression profiles of circulating cells for objectified ischemic coronary artery disease in patients with complaints suspect for angina pectoris

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

Summary

ID

NL-OMON40975

Source
ToetsingOnline

Brief title
MYOMARKER

Condition

- Coronary artery disorders

Synonym
angina (pectoris), ischemic coronary artery disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: biomarkers, coronary artery disease, myocardial ischemia

Outcome measures

Primary outcome

Parameter; Extracellular vesicle protein- and miRNA-concentration, and gene expression profiles in circulating cells.

Endpoint: Objectified ischemic coronary artery disease, determined by radionuclide myocardial perfusion imaging (Rubidium-82).

Secondary outcome

Follow-up: all-cause mortality, cardiovascular death, non-fatal MI, coronary revascularisation, stroke, and peripheral vascular interventions.

Study description

Background summary

Coronary artery disease (CAD) is a leading cause of morbidity and mortality in de the Netherlands and prevalence of angina in western populations is high. Early diagnosis of CAD is essential, because of improvement in prognosis following timely interventions. On the other hand, early rule out of CAD reduces costs (e.g. diagnostic procedures, hospital admissions) and patient burden. However, the current diagnostic approach for suspected CAD in the cardiology outpatient clinic is based on an individuals* pre-test probability (PTP) of having CAD, and thus heterogeneous, due to dependency of diagnostic test accuracy on PTP. Hence, there is a clinical need for sensitive biomarkers for ischemic CAD. Recently, both plasma extracellular vesicle (EV) protein/miRNA expression and plasma gene-expression profiles of circulating cells are reported to have changed expression in hypoxic myocardium, and are therefore potentially valuable sensitive diagnostic and/or prognostic biomarkers for ischemic coronary artery disease.

Study objective

To analyse the diagnostic and prognostic value of plasma EV protein/miRNA and

gene expression profiles of circulating cells for objectified ischemic coronary artery disease in patients with complaints suspect for angina pectoris

Study design

Prospective diagnostic and prognostic cohort study.
Ahead of radionuclide myocardial perfusion imaging (rMPI), venous blood (5x10cc and 2x4.5cc) will be obtained from the intravenous cannula (peripheral) that is already inserted (standard clinical procedure) during preparation for rMPI. The blood will be collected for the assessment of microvesicles and circulating cells. In addition, patients will be asked to fill out a (short) questionaire regarding nature and intenstity of symptoms and cardiovasculair risk factors. Patients will be contacted for follow-up after 1 year and 2 years (primary and secondary cardiovascular events).

Study burden and risks

As part of the study, 7 tubes of venous blood (60cc in total) will be withdrawn from an already inserted intravenous peripheral access (canula). Additional harm to the patient is not expected since insertion of the intravenous canula is part of standard clinical practice during prepartion for radionuclide myocardial perfusion imaging. Any break in the skin carries a small risk of infection or hematoma formation. No extra site visit of physical examination is required, and the study will not affect the treatment of the patients. For the purpose of follow-up, the patient will be contacted (by mail or telephone) after 1 year and 2 years.

Contacts

Public
Meander Medisch Centrum

Maatweg 3
Amersfoort 3813 TZ
NL
Scientific
Meander Medisch Centrum

Maatweg 3
Amersfoort 3813 TZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients (age >18yr), who are being evaluated in the Meander Medical Center cardiology outpatient clinic with symptoms suggestive for ischemic coronary artery disease, and who will undergo radionuclide myocardial perfusion imaging (rMPI) as indicated by their own cardiologist.

Exclusion criteria

- Age <18 years at time of inclusion
- Patients from whom no informed consent is obtained
- Incapacitated adults; language barriers or other obstacles for full understanding of the study objectives.

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):	12-08-2014
Enrollment:	1265
Type:	Actual

Ethics review

Approved WMO Date:	26-06-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-10-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL48721.100.14