Study of the relation between biomarker patterns and the incidence of recurrent coronary events during 1-year follow-up in patients who were hospitalised for an acute coronary syndrome; BIOMarker Study to identify the Acute risk of a Coronary Syndrome (BIOMArCS)

Published: 16-08-2007
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Describe the relation between patterns in biomarkers of vascular inflammation, plaque instability and hypercoagulability and the incidence of recurrent ACS

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

Summary

ID

NL-OMON43706

Source
ToetsingOnline

Brief title
BIOMArCS

Condition

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

Synonym
coronary artery disease; 'furring' of the coronary arteries

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Interuniversitair Cardiologisch Instituut Nederland,Nederlandse Hartstichting

Intervention

Keyword: - acute coronary event, - atherosclerosis, - biomarker, - repeated measurements

Outcome measures

Primary outcome

Primary determinants ('study parameters'): biomarkers of vascular inflammation,

plaque instability and hypercoagulability

The primary endpoint is a composite of cardiovascular mortality , non-fatal

acute coronary syndrome or unplanned coronary revascularization due to

progressive angina pectoris during 1-year follow-up.

Secondary outcome

Secondary endpoints are

1. A composite of cardiovascular mortality and non-fatal acute coronary

syndrome only;

2. A composite of cardiovascular mortality, non-fatal acute coronary syndrome

and all coronary revascularizations (including staged/planned procedures);

3. A composite of cardiovascular mortality, non-fatal acute coronary syndrome,

unplanned coronary revascularization, re-hospitalization for angina or stroke.

Study description

Background summary

Although current primary and secondary cardiovascular disease (CVD) prevention programs are effective on group level, they largely fail to identify the individual who is at high risk of developing an acute coronary syndrome (ACS), and the period(s) during which this risk is serious and imminent. In fact, these programs insufficiently utilise knowledge of the pathophysiology of CVD and ACS. In the lifetime of CVD patients prolonged periods of stability, with minimal plaque progression and low risk of coronary events, are succeeded by periods of active (vascular) inflammation and plaque instability, during which coronary events are highly likely to occur. If these vulnerable periods can be detected, treatment might be timely intensified to prevent the event from occurring.

This study is the first in a series in which we will evaluate if biomarkers of vascular inflammation, plaque-instability and hypercoagulability (repeatedly measured by blood sampling) can be used to recognise episodes of coronary vulnerability.

Study objective

Describe the relation between patterns in biomarkers of vascular inflammation, plaque instability and hypercoagulability and the incidence of recurrent ACS

Study design

This is an observational, descriptive, multicenter clinical trial

Study burden and risks

Patients have to visit the outpatient clinic regulary (maximum 16 times extra than standard care) during a period of 1 year follow-up.

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

- At least 40 years of age
-A high-risk profile with regard to the occurrence of primary endpoint during follow-up, as indicated by the presence of at least 2 points. 2 Points are given in case of presence of one the following risk factors: Age * 75 years, diabetes mellitus, prior angina, prior myocardial infarction, prior cerebrovascular disease, peripheral arterial disease. 1 Point is given in case of presence of one the following risk factors: Age > 65 years in men and > 70 years in women, Hypertension, Hypercholesterolemia, Current smoking, Microalbuminuria

Exclusion criteria

- Myocardial ischemia precipitated by a condition other than atherosclerotic coronary artery disease
- Severely-impaired left ventricular function or end-stage congestive heart failure NYHA-class III or IV
- Severe chronic kidney disease
- Co-existent condition associated with a life-expectancy <1 year, or otherwise unlikely to appear at all scheduled follow-up visits

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):	01-01-2008
Enrollment:	900
Type:	Actual

Ethics review

Approved WMO Date:	16-08-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-05-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-07-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	Nederlands Trialregister NTR1698
CCMO	NL17944.078.07