Study of the evolution of biomarker patterns following admission for an acute coronary syndrome

Published: 16-08-2007
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Describe patterns of biomarkers of vascular inflammation, plaque-instability and hypercoagulability shortly after admission for ACS

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

Summary

ID

NL-OMON30866

Source
ToetsingOnline

Brief title
Biomarker patterns after admission for acute coronary syndromes

Condition

- Coronary artery disorders

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: ICIN (Interuniversitair Cardiologisch Instituut Nederland)

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

Primary endpoint (outcome): absent; this is not an outcome-trial

Secondary outcome

There are no secondary 'study parameters' or endpoints

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 patterns of biomarkers of vascular inflammation, plaque-instability and hypercoagulability shortly after admission for ACS

Study design

This is an observational, descriptive, multicenter clinical trial

Study burden and risks

For the purpose of this study, patients have to visit the outpatient clinic 7 times during a period of 1 year. Four of these visits cannot be considered a routine control visit.

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
- Admission for an acute coronary syndrome
- At least two of the following high-risk features: age ><=65 (70) in men (women), diabetes mellitus, hypertension, hypercholesterolemia, current smoking, prior angina, prior myocardial infarction, prior cerebrovascular disease, peripheral arterial disease, or 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:	250
Type:	Actual

Ethics review

Approved WMO

Date:	16-08-2007
Application type:	First submission

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
CCMO	NL18076.078.07