Thrombotic markers as predictors for recurrent cardiovascular events after the acute coronary syndrome

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Objective:The hypothesis of this study is that laboratory markers for blood coagulation, platelet activity and inflammation may help to identify patients at risk for a recurrent cardiovascular event after ACS. Secondary, we expect to find...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON38237

Source
ToetsingOnline

Brief title
TRACS

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
heart disease, myocardial ischemia

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Hartstichting

Intervention

Keyword: Acute coronary syndrome, cardiovascular risk, Markers, Thrombosis

Outcome measures

Primary outcome

Study parameters/endpoints:

A panel of markers of coagulation will be determined (microparticles, hsCRP, interleukins, NT pro-BNP, D-dimer, flTFPI, protein S, coagulation factors) and different techniques will be used (thrombin generation and elisa based on recombinant nanobodies). The combined end points comprise cardiovascular death, recurrent myocardial infarction, a secondary coronary intervention (PCI or CABG) and ischemic stroke.

Secondary outcome

not applicable

Study description

Background summary

Rationale:
Ischemic heart disease is the leading cause of death worldwide, killing over 6 million individuals each year, with an increasing margin into 2030. By far the most frequent cause of ischemic heart disease is coronary atherosclerosis with vascular plaque formation. Plaque disruption with superimposed thrombosis is the main cause of the acute coronary syndromes (ACS) of unstable angina, myocardial infarction, and sudden death. The number of deaths from a myocardial infarction in the period 1980-2008 decreased by 62% from 20.352 to 7.792 and is mainly due to faster and more adequate treatment options. However, survivors of coronary heart disease have an increased risk for recurrent coronary events, other vascular events and downstream consequences of coronary events. Though not all patients will have a recurrent cardiovascular event, up till now there

are no methods for selecting those patients with the highest risk. Although platelets are usually considered the most important factor in arterial thrombosis, activated by rupture of an atherosclerotic plaque, there have been recent new insights pointing more towards the importance of coagulation factors in this process. Multiple plasma markers of activated haemostasis have been studied in thrombotic disorders, more specifically in ACS. Many studies have reported elevated plasma concentrations of haemostatic markers in ACS patients, however up till now only few have tried to translate these results to the clinic.

Study objective

Objective:
The hypothesis of this study is that laboratory markers for blood coagulation, platelet activity and inflammation may help to identify patients at risk for a recurrent cardiovascular event after ACS. Secondary, we expect to find differences in these markers between the patient groups with unstable angina and acute myocardial infarction, based on the pathophysiological differences between these diseases. Ultimately, an improved risk assessment may lead to a more balanced choice for secondary preventive therapy in these patients.

Study design

Study design:
Prospective cohort study in 350 patients with the ACS.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
There are 3 venipunctures carried out. The first blood sampling is at the time of diagnosis, either in the ambulance or at the cardiac care unit (academic hospital Maastricht or Atrium hospital Heerlen), prior to medication or intervention. The second blood sampling is after 1 month and the last time is 6 months after diagnosis. For the venipuncture at 1 and 6 months patients will have to bring a visit to the heart and vascular center of the academic hospital Maastricht or Atrium hospital Heerlen. At 12 and 24 months telephone questionnaires will be conducted.
Regarding the control population, only the blood already collected in the ambulance will be used. No further venipunctures will be carried out.

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

Study population = Patients >18years who meet the criteria of the acute coronary syndrome: unstable angina, non ST segment elevation myocardial infarction, ST segment elevation myocardial infarction. ;Control population = Patients >18years who DON'T meet the criteria of the acute coronary syndrome, form which the ambulance personal drew blood during transport to the hospital because of high suspicion of ACS.

Exclusion criteria

Study population =
1. Inability to attend follow-up visits at one of the participating hospitals at 1 and 6 months after inclusion.
2. Patients using anticoagulant medication (coumarines).;Control population = Patients using anticoagulant medication (coumarines)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2012
Enrollment:	585
Type:	Actual

Ethics review

Approved WMO Date:	18-08-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-05-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-06-2012
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
CCMO	NL35413.068.11