Study of Myocardial Infarctions in Leiden - Platelets (SMILE-Platelets). Value of platelet function tests in the prediction of cardiovascular events

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To examine whether platelet hyperreactivity, as assessed by various platelet activation or function tests, could explain recurrence of cardiovascular events among patients that suffered a first MI.To assess which (combination of) platelet activation…

Ethical review	Approved WMO
Status	Pending
Health condition type	Myocardial disorders
Study type	Observational invasive

Summary

ID

NL-OMON31348

Source
ToetsingOnline

Brief title
SMILE-Platelets project

Condition

- Myocardial disorders

Synonym
cardiovascular diseases, Myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

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

Intervention

Keyword: Antiplatelet medication, Cardiovascular disease, Platelet function tests

Outcome measures

Primary outcome

The composite of cardiovascular death; nonfatal MI; nonfatal ischemic stroke;

unstable angina; coronary, carotid or peripheral revascularisation; and

peripheral artery disease needing amputation as a result of ischemia.

Secondary outcome

NA

Study description

Background summary

Recurrent cardiovascular events may be predicted by (a combination of) platelet activation or function tests among patients that suffered a first myocardial infarction (MI).

Study objective

To examine whether platelet hyperreactivity, as assessed by various platelet activation or function tests, could explain recurrence of cardiovascular events among patients that suffered a first MI.
To assess which (combination of) platelet activation or function tests most reliably predict recurrent cardiovascular events among patients that suffered a first MI.

Study design

Prospective cohort study (and a nested case-control study within this same cohort) among patients who survived a first MI.
Cases: patients with recurrent cardiovascular disease after first MI
Controls: patients without recurrent cardiovascular disease after first MI

Study burden and risks

The burden associated with participation is very low: participants have to come once to our research centre. They will be asked to complete one questionnaire and a venapuncture will be performed. There are no risks associated with participation.

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

Cases: recurrent cardiovascular event after inclusion in the SMILE-study
Control subjects: event-free after inclusion in the SMILE-study

Exclusion criteria

Severe neuropsychiatric disease

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2007
Enrollment:	400
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL18657.058.07