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The association between new and established cardiovascular serum markers

Submission date 19/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/12/2005	**Overall study status** Completed	
Last Edited 05/11/2008	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR376

Study information

Scientific Title
The association between new and established serum markers in cardiovascular disease

Study objectives
We hypothesise that our newly discovered serum risk markers are positively associated with the presence of cardiovascular diseases.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised, single-blind, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
In the groups AMI, SAP, UAP and controls, the marker concentrations of several potential new risk markers for cardiovascular diseases will be evaluated at inclusion, after 6 months, and after 12 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
(Recurrent) cardiovascular disease e.g. myocardial infarction (MI), SAP, UAP, mortality

Secondary outcome measures

No secondary outcome measures

Overall study start date
01/11/2004

Completion date
01/05/2007

Eligibility

Key inclusion criteria
Groups of acute myocardial infarction (AMI), stable angina pectoris (SAP), unstable angina pectoris (UAP) and controls will be formed (n = 120). All participants will donate a venous blood sample at inclusion, and after 6 and 12 months. Marker concentration will be evaluated in these blood samples.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
120

Key exclusion criteria
1. Unable to give informed consent
2. Cardiovascular disease (CVD) less than 6 months
3. Auto-immune diseases
4. Malignancies
5. Renal insufficiency (less than 40 ml/min creatinine clearance)

Date of first enrolment
01/11/2004

Date of final enrolment
01/05/2007

Locations

Countries of recruitment
Netherlands

Study participating centre

University Hospital of Maastricht
Maastricht
Netherlands
6202 AZ

Sponsor information

Organisation
University Hospital Maastricht (AZM) (The Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.unimaas.nl/

ROR
https://ror.org/02d9ce178

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Heart Foundation (Nederlandse Hartstichting) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration