

The association between new and established cardiovascular serum markers

Submission date 19/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/11/2008	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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