"BIOMarker study to identify the Acute risk of a Coronary Syndrome (BIOMArCS)" and "Hartinfarct-biomarker studie (deel II)".

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1. Vascular inflammation becomes activated several days to weeks before an acute coronary syndrome; 2. Biomarkers of vascular inflammation, distorted lipid metabolism, endothelial dysfunction, diminished endothelial regenerative capacity,...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27734

Bron
Nationaal Trial Register

Verkorte titel
BIOMArCS

Aandoening

Acute Coronary Syndrome (Unstable Angina, Non ST-Elevatiom Myocardial infarction and ST-elevation Myocardial Infarction)

Ondersteuning

Primaire sponsor: Principal investigator: Prof. Eric Boersma, PhD, MSc, FESC. Department of Cardiology, unit Clinical Epidemiology, ErasmusMC Rotterdam, The Netherlands
Overige ondersteuning: 1) Netherlands Heart Foundation
2)Interuniversity Cardiology Institute Netherlands(ICIN)/(Royal Netherlands Academy of Arts and Sciences)
3) ErasmusMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is a composite of cardiovascular mortality or a clinical diagnosis of a non-fatal acute coronary syndrome during 1-year follow-up.

Toelichting onderzoek

Achtergrond van het onderzoek

BIOMArCS is a multi-centre, prospective, observational study with 1-year follow-up of 700 patients after ACS, either with or without ST-elevation. Patients with at least two cardiovascular risk factors are included, so that the primary endpoint (cardiovascular mortality or repeat non-fatal ACS) is likely to occur in 10% of the cohort. Venapuncture is planned every fortnight during the first half-year and monthly thereafter. Biomarker patterns prior to the endpoint will be determined at the end of follow-up in the (suspected) 70 cases and compared to 210 event-free, matching controls.

Doel van het onderzoek

1. Vascular inflammation becomes activated several days to weeks before an acute coronary syndrome;

2. Biomarkers of vascular inflammation, distorted lipid metabolism, endothelial dysfunction, diminished endothelial regenerative capacity, hypercoagulability and myocardial ischemia become elevated before the event;

3. Hence, serial biomarker measurements might be used to identify vulnerable periods in the life-time of patients with established cardiovascular disease (as well as in individuals with prevalent but yet unrecognised cardiovascular disease), during which they are at increased risk of developing an acute coronary syndrome;

4. An imminent acute coronary syndrome might be prevented by future intensified medical treatment, or by a percutaneous coronary intervention.

Onderzoeksopzet

Total follow-up duration is 1 year. Patient interviews and blood sample collection and are planned during hospital admission for and acute coronary syndrome and subsequently every two week during the first half year of follow-up and monthly during the last half year of

follow-up.

Onderzoeksproduct en/of interventie

None, strictly observational post-ACS study.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Complaints of typical ischemic chest pain, lasting 10 minutes or more within the preceding 24 hours prior to presentation;

2a. ECG: (Non-)persistent ST segment elevation > 1.0 mm in two or more contiguous leads or dynamic ST segment depression > 1.0 mm in two or more contiguous leads;

OR

2b. CK-MB or Troponin I > the upper normal limit or Troponin T > 0.05 µg/L (ng/ml);

3. Age ≥ 40 years;

4. Presence of ≥ 2 conventional risk factors
(Age ≥ 65 years in males, age ≥ 70 years in females, diabetes mellitus, hypertension, hypercholesterolemia, current smoking, prior angina, prior myocardial infarction, prior cerebrovascular disease, peripheral arterial disease or microalbuminuria*, positive family history of coronary artery disease §);

5. Written informed consent.

* Defined as >2.5-25 mg albumin/mmol creatinin for men and >3.5-35 mg for women, or >20-200 mg/l urinary albumin concentration in a single urine sample.

§ Angina pectoris, myocardial infarction, or sudden abrupt death without obvious cause, before the age of 55 in a first-degree blood relative.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Myocardial ischemia precipitated by a condition other than atherosclerotic coronary artery disease (e.g. arrhythmia, severe anemia, hypoxia, thyrotoxicosis, cocaine abuse, severe valvular disease, hypotension);

2. Left ventricular ejection fraction < 30 % or end-stage congestive heart failure (NYHA class III or IV);

3. Renal dialysis or severe chronic kidney disease with measured or calculated GFR (Cockroft-Gault or MDRD4 formula) of < 30 ml/min/1.73 m2;

4. Co-existent condition with life-expectancy < 1 year or otherwise not expected to complete follow-up.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2008
Aantal proefpersonen:	700
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-03-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1614
NTR-old	NTR1698
Ander register	MEC/ICIN/NHS : 2007-185/07101/2007B012
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A