Psycho-biochemical perspective on non-acute coronary syndrome: A prospective study of novel risk factors.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON31887

Source
ToetsingOnline

Brief title
Non-acute coronary syndrome, a psycho-biochemical perspective

Condition

- Coronary artery disorders

Synonym
Non-acute coronary syndrome, vascular irregularities

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: biomarkers, prospective, psychological, vascular irregularities

Outcome measures

Primary outcome

MACE (mortality, MI, percutaneous coronary intervention (PCI) or coronary artery bypass graft surgery (CABG)), and patient perceived symptoms (angina complaints, fatigue, health status, global mood)

Secondary outcome

The secondary aim is to investigate the correlation and the stability over time between Type D versus non-Type D persons and biomarkers in patients with AC-CAD.

Study description

Background summary

Type D personality (increased negative affect combined with social inhibition) is associated with a 4-fold increased risk of mortality and adverse health outcomes, above and beyond traditional risk factors in patients with cardiovascular disease (CVD). However, we know little about its mechanisms, or prognosis in the early development of CVD.
Acute coronary syndromes (ACS) such as unstable angina, or myocardial infarction (MI) are often the result of a disruption of a stenotic vulnerable plaque, leading to thrombotic complications. Plaques with moderate (<50%) stenosis pose a significant risk for ACS development and mortality. Nevertheless risk stratification in patients with moderate stenosis and non-acute cardiac symptoms remains largely unexplored.
The atherosclerotic state preceding a cardiovascular event is a systemic inflammatory disease. An increased inflammatory state as well as prothrombotic factors are emerging biomarkers for plaque development, instability, and worse prognosis. Type D personality has been related to an altered inflammatory profile in chronic heart failure.

Study objective

The goal of the proposed study is to investigate a preexisting psycho-biochemical risk profile for major adverse cardiovascular events (MACE) and patient perceived symptoms in a group with angiographically confirmed, but non-acute, coronary artery disease (AC-CAD). Characterized by mild stenosis and vascular irregularities.

Study design

Psychosocial variables and biomarkers will be measured at baseline and at one year. The multifactorial risk profile is based on a personality risk profile (Type D personality, and other negative affect markers), traditional risk factors (metabolic syndrome, demographic variables), and biomarkers of inflammation and thrombosis. MACE and patient perceived symptoms at two-year follow-up serve as the outcome measures. Finally, the interrelationship between Type D personality and the biomarkers at baseline and at follow-up will be assessed to further evaluate preexisting risk factors and their changes over time.

Study burden and risks

The proposed study incurs no extra risk to patients, as they receive no additional treatment/ tests no will any treatment be withheld from them compared to patients who choose not to participate or are excluded on the basis of the exclusion criteria. Venapunctures (2) will take place, preferentially combined with standard assessments for the clinical management of patients. Patients will complete a set of psychological questionnaires, which is estimated to take 1 hour. These questionnaires can be filled-out at home and returned by pre-stamped envelope.

Contacts

Public
Universiteit van Tilburg

Warandelaan 2
5000 LE Tilburg
NL
Scientific
Universiteit van Tilburg

Warandelaan 2
5000 LE Tilburg
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

500 patients from the TweeSteden Hospital Tilburg with angiographically established vascular irregularities (moderate stenosis 10-50%) on one main coronary artery. Potentially eligible patients will be screened based on angiograms and medical records not older than 3 months.

Exclusion criteria

Exclusion criteria: severe coronary stenosis (>50% obstruction), Left main coronary artery plaque < 50%. Previous history of cardiac events, such as MI, PCI or CABG, psychiatric illness other than affective/anxiety disorders, acute infection, being treated with anti-inflammatory drugs other than low-dose aspirin, severe chronic kidney failure (on dialysis or a creatinine level > 250 µmol/liter), chronic systemic disease and treated with corticosteroids or chemotherapy, insufficient knowledge of the Dutch language.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-01-2009
Enrollment:	500
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	12-01-2009
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL22258.008.08