Regional Activation of Leukocytes in Coronary artery disease And Diabetes mellitus (REAL-CAD)

Published: 03-01-2007
Last updated: 20-05-2024

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

Summary

ID

NL-OMON30068

Source
ToetsingOnline

Brief title
REAL-CAD

Condition

- Coronary artery disorders
- Glucose metabolism disorders (incl diabetes mellitus)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerosis, coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis

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

Intervention

Keyword: atherosclerosis, Diabetes mellitus, Leukocytes

Outcome measures

Primary outcome

In this study the inflammation (leukocyte activation markers and complement components) in different vascular beds end the relation with triglycerides and glucose will be investigated in different patient groups.

In addition MBL genotypes and serum levels of these patients will be determined to get more insight in the differences between the groups.

Secondary outcome

Not applicable.

Study description

Background summary

Atherosclerosis is one of the major causes of death in the world. Lipoproteins, triglycerides (TG), fatty acids and glucose are able to induce leukocyte activation in vitro and in vivo, which is obligatory for the development of atherosclerosis. Therefore, inhibition of leukocyte activation and/or endothelial cell activation is a promising target for intervention in the struggle against atherosclerosis. Complement component 3 (C3) and Mannose Binding Lectin (MBL) are other inflammatory factors which plays a role in the process of atherosclerosis as both have been linked to CAD.
Our knowledge concerning these inflammatory factors and the relation to atherogenesis is limited. In recent studies regional differences in leukocyte activation was found during catheterization in subjects with unstable angina compared to patients with stable angina and healthy subjects. Higher leukocyte activation has also been shown in type 2 diabetics compared to healthy controls.
There are no data available on the mechanism behind the (regional) differences in leukocyte activation. In addition, only a few publications have been

released on the role of neutrophils in the process of atherosclerosis. Most groups have studied monocytes and lymphocytes because these are the cells that are present in the plaque.
We propose that the activation of neutrophils is one of the earliest events in the process of atherosclerosis and that complement activation and regional differences in lipoprotein and glucose concentrations may be involved.

Study objective

1. The primary aim of REAL CAD is to determine regional differences of leukocyte
activation in different vascular beds in vivo.
2. The secondary aim is to investigate differences in leukocyte activation between
diabetic and CAD subjects and patients suffering from both.
3. The third aim is to investigate the relationship between complement components, triglycerides and leukocyte activation markers in order to gain more insight into the causative processes leading to activation of leukocytes.
4. The fourth aim is to get more insight in the MBL genotypes and serum levels of
CAD and/or diabetic patients and the *healthy* groups included in our study.

Study design

Patients, who visit the outpatient clinics of the department of cardiology and are scheduled to undergo a diagnostic coronary catheterization, will be asked to participate in this study. Written informed consent will be obtained from each participant. Subjects must give a separate consent for the DNA blood sampling. Patients will not be paid for participation in this study.
The patients will be asked to visit the laboratory for blood sampling in order to determine baseline characteristics and to obtain DNA. Subsequently, they will be scheduled for catheterization, which they will undergo after a 10 hrs fasting period. During catheterization blood sampling shall occur at five different regions, which are the abdominal aorta just above the bifurcation, aorta ascendens, both coronaries and a peripheral vein in the left or right arm.

Study burden and risks

Except for the risks of coronary catheterization there are no/little risks for the patients in this study. The patients are already scheduled to undergo a coronary catheterization and by means of the catheter blood sampling can occur. However, there shall be an intravenous blood sample in a peripheral vene in the arm.

The time burden will also be minimal; during the visit in which the cardiologist and the patient decide to do a catheterization, the patient will be asked to participate. If they agree on participation, the investigator will come to the patient in order to ask the family history and the medication as well as to determine the blood pressure, weight, length, waist. This shall take 15 minutes.

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

Subjects scheduled to undergo a coronary catheterization
Aged >18 and <75 years
BMI < 35 kg/m2

Exclusion criteria

Emotionally and intellectually not capable to decide about participation in the study and the consequences of participation. Subjects who are not able to understand the patient information
Unstable angina pectoris
CABG or PTCA during the last 6 months
Alcohol use > 2 units/day
Aberrations in kidney, liver and thyroid function
Use of any experimental medication within 6 months of the catheterization
The use of immunosuppressive drugs

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-01-2007
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	03-01-2007
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL13633.101.06