Circulating blood cell populations in pateints with Diabetes mellitus and coronary artery disease: studies on cellular functions

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

Summary

ID

NL-OMON30945

Source
ToetsingOnline

Brief title
VERAD2B

Condition

- Coronary artery disorders
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
coronary artery disease, diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: blood cells, coronary artery disease, diabetes mellitus

Outcome measures

Primary outcome

Possible differences between the study groups in number, phenotype or function

will be statistically analyzed.

Secondary outcome

not applicable

Study description

Background summary

Occlusion of a coronary artery leads to ischemia and to the consecutive death of myocytes and vascular structures in the supplied region of the heart. The development of new blood vessels in response to tissue ischemia constitutes a natural repair mechanism that maintains tissue perfusion required for proper organ function. The functional recovery of myocardium is partly dependent on the formation of new blood vessels to supply oxygen and nutrients to myocardium. Different cardiovascular risk factors such as diabetes mellitus alter structure and function of existing blood vessels (atherogenesis) and impair the formation of new ones (angiogenesis). For this reason, many experimental and clinical therapies have mainly focused on understanding how to overcome the negative influence of diabetes mellitus and how to limit myocardial ischemia by stimulating the formation of new blood vessels. This process of vascular growth is facilitated by monocytes, lymphocytes and bone marrow-derived progenitor cells. The proper function of these cells is important. Cardiovascular risk factors such as diabetes mellitus can negatively influence the function of these cells.

Study objective

Our aim is to characterize the functional properties of circulating cells (monocytes, lymphocytes, and progenitor cells) in patients with chronic coronary artery disease (CAD) and acute myocardial infarction (AMI). Likewise, we wish to characterize the role of diabetes mellitus (DM) on cellular function, both independent of CAD and together.

Study design

Blood samples (100 ml) will be collected from subjects by venupuncture. Monocytes, lymphocytes and progenitor cells will be specifically isolated. Cells will be characterized for their number and phenotypic characteristics. In addition, they will be subjected to functional assays including a chemotaxis assay to analyze their response towards various growth factors.

Study burden and risks

Research methods are minimally invasive, therefore there is a neglijible risk for the patients.

Relevance for medicine: These data will help to better understand the process of vascular repair and vascular growth in patients with coronary atherosclerosis. Moreover, it will provide valuable information on the role of cardiovascular risk factors such as diabetes on the process of vascular growth. This will represent a solid background for the development of novel anti-atherosclerotic therapies.

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

•Diabetes mellitus: Diabetes type II, compensated with diet and/or oral medication.
•CAD: History of coronary artery disease >2 years, no myocardial infarction in the last 6 months.
•AMI: >3-fold increase of CK (CK-MB) levels. Patients with coronary artery disease in their early period after Acute Myocardial Infarction (day 4 - 7 post-infarction) will be recruited.
•Controls: patients diagnosed with hypertension, arrhythmias and/or heart valvular diseases; subjects should be age-matched with the above mentioned groups (subjects <45 years or >75 years old will be excluded).

Exclusion criteria

•Anemia (Hb<8 g/L)
•Acute infectious diseases (e.g., pneumonia, urinary tract infections, anaphylactic shock etc.)
•Acute inflammation other than AMI (elevated leukocyte number)
•Acute conditions (surgery, stroke, thromboembolism etc)
•Single or multiorgan failure (heart failure NYHA III/IV, lung, liver, kidneys)
•Chronic inflammatory diseases (chronic kidney diseases, rheumatoid arthritis)
•Malignant diseases (or recent history of malignant diseases <1 year)
•Malignant arterial hypertension
•Hormonal treatment (thyroid hormones-T3/T4 not included) or anti-inflammatory drugs
•Genetic disorders (Down syndrome, X&Y chromosome syndrome), family hypercholesterolemia, genetic dyslipidemia
•Psychiatric abnormalities

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-06-2008
Enrollment:	136
Type:	Actual

Ethics review

Approved WMO Date:	02-07-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL17185.068.07