Innate immunity and vascular complications in type II diabetic South-Asian immigrants

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

Summary

ID

NL-OMON30311

Source
ToetsingOnline

Brief title
Hindinef II

Condition

- Coronary artery disorders
- Retina, choroid and vitreous haemorrhages and vascular disorders
- Nephropathies

Synonym
cardiovascular disease, diabetes, nephropathy, retinopathy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: complement, diabetes, innate immunity, vascular complications

Outcome measures

Primary outcome

- prevalence / progression nephropathy

- prevalence retinopathy

- prevalence ischemic heart disease

- prevalence peripheral vascular disease

- prevalence cerebral vascular accidents

- intima media thickness of the carotid artery

- pulse wave velocity analysis

Secondary outcome

no

Study description

Background summary

South-Asian immigrants in a western society have an increased risk of developing diabetes and associated cardiovascular complications. Beside traditional risk factors like glycaemic control, hypertension, lipid disturbances and smoking, there is an increasing body of evidence that the complement system, belonging to innnate immunity, is involved in the pathogenesis / progression of these vascular complications. Complementproducts have been detected in kidneys of diabetic patients and in atherosclerotic plaques. Complement activation products have been detected in the urine of patients with diabetic nephropathy. More recently, an association between serumlevels of MBL (Mannan, Binding Lectin, the recognitionmolecule of the lectin pathway of complement activation) and diabetes was reported. MBL levels were increased in diabetic persons compared to healthy control persons. In

addition, the serum MBL level were positively correlated with the incidence of nephropathy and cardiovascular disease. In type 2 diabetics a positive correlation between MBL levels and (cardiovascular) mortality was also found. Mutations in the factor H gene, an inhibitor of the complementsystem, have recently been associated with an increased incidence of ischemic heart disease.

Study objective

the study aims to answer the following question:are components of innate immunity in general, and the complementsystem in particular, correlated with and usefull as predictors for the occurrence of macro- and/or microvascular complications in a high-risk population of type II diabetic South Asian immigrants?

Study design

It is a follow-up study of the previously conducted Hindinef study. This study included South-Asian immigrants (both diabetic and non-diabetic) and was performed between 1998 and 2000. Clinical information as well as blood- and urine samples have been collected from all these persons. We will study innate immunity in these "baseline"samples. Next we aim to recall all the diabetic subjects and score the progression of diabetic nephropathy and the incidence of vascular complications. We will investigate the association between immunological parameters (complement activation products, leucocyte activation, cytokine profiles) and the progression of complications (nephropathy, retinopathy, atherosclerosis).

Study burden and risks

the testperson visits our outpatient clinic. During this visit we perform a questionnaire - which has been sent to the homeaddress-, a brief physical examination, venapuncture, sampling of urine, EKG and fundusphotography. In this visit, permission is asked for a second visit in which the carotid artery intima media thickness is measured and pulse wave velocity is analysed

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 type II

Exclusion criteria

geen

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	169
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL15586.058.06