Generation of a bio-databank for the study of the etiology of type 2 diabetes mellitus and related diseases and complications.

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Identification of genetic risk factors for development of type 2 diabetes, diabetes related diseases and complications. Furthermore the examination of the relationship between genetic variation, biochemical factors, environmental factors (obesity…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON30511

Source
ToetsingOnline

Brief title
DNA for Diabetes Genes.

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Diabetic complications

Synonym
Diabetes Mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Parelsnoer initiatief en Diabetes Fonds Nederland

Intervention

Keyword: Diabetes Mellitus, Epidemiology, Genetics

Outcome measures

Primary outcome

The construction of a bio-databank containing genetic profiles as well as

biochemical and clinical characteristics of the patients will be the endpoint.

This bio-databank and the occurrence of diabetes complications or diabetes

related diseases will be used to calculate the risk of developing type 2

diabetes.

Secondary outcome

not applicable

Study description

Background summary

Several genetic factors of type 2 diabetes mellitus have been identified during the past years. However, progress has been slow. Furthermore the effect size of the known genetic susceptibility factors has shown to be relatively low. This suggests that only a combination of several genetic risk factors in association with a detrimental life style will eventually lead to chronic hyperglycaemia, which is the general hallmark of type 2 diabetes mellitus. The low impact of individual genetic defects implicates that only sufficiently powered studies (i.e. with large sample sizes) will be able to detect associations between a gene and the disease. Currently even less is known about the impact of these genetic factors on the development of diabetic complications, mainly because the current studies are underpowered due to insufficient sample sizes. Increased knowledge about the pathogenesis of the disease and disease-related

complications might provide better prevention and treatment options for those at risk. Moreover, it might enable us to halt the rapidly growing number of patients worldwide.

Study objective

Identification of genetic risk factors for development of type 2 diabetes, diabetes related diseases and complications. Furthermore the examination of the relationship between genetic variation, biochemical factors, environmental factors (obesity etc) and the development of type 2 diabetes, diabetes related diseases and complications.

Study design

Observational cohort study

Study burden and risks

Informed consent to search medical records and a donation of four blood samples (40 ml) will be asked of the participants. Because this will be done during one of the regular visits, the risk as well as the burden for the participants is negligible. Part of the donated blood samples will be stored for future research in a Diabetes Bio-databank. Benefit for the participants will be the identification of novel risk factors for type 2 diabetes which may facilitate the development of better prevention and treatment options for those at risk.

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

Having type 2 diabetes and participating in the diabetes care system West-Friesland.

Exclusion criteria

No diabetes type 2 or no participant of the Diabetes care system West-Friesland.
Type 1 diabetes or requiring insulin therapy within one year after diagnosis.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2008
Enrollment:	5000

Type:	Actual

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL14692.029.07