The New Hoorn Study - prevalence and determinants of impaired glucose regulation

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A. To determine prevalence and determinants of impaired glucose regulation 1. To study the prevalence of impaired glucose regulation and type 2 diabetes in the general population aged 40 to 65 years, and to compare these prevalence rates with those...

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

Summary

ID

NL-OMON30116

Source
ToetsingOnline

Brief title
NHS

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: farmaceutische industrie en opdrachtgever (EMGO),Novartis

Intervention

Keyword: algemene populatie, determinants, diabetes mellitus type 2, prevalence

Outcome measures

Primary outcome

Diabetes mellitus type 2 or impaired glucose metabolism yes/no

Secondary outcome

- determinants of glucose metabolism

- beta-cell function and determinants of beta-cell function

Study description

Background summary

Prevalence and determinants of impaired glucose regulation
In 1989 a large study on the prevalence of type 2 diabetes (DM2) and impaired glucose tolerance (IGT) in the general population of the Netherlands was performed (The Hoorn Study). Results showed that the prevalence of DM2 and IGT (assessed with an OGTT) in 2484 participants aged 50 to 75 years was about 20%. Age, family history of diabetes and waist-to-hip ratio (WHR) were the most important determinants of glucose metabolism.
Due to various lifestyle and demographic changes, the prevalence of DM2 increased worldwide. In addition, these changes have led to a change in the phenotype of DM2. Despite these changes, no large population-studies aimed to determine the prevalence of impaired glucose regulation and determinants of DM2 in the Netherlands have been carried out in the last 15 years.
Beta-cell function in the general population.
Beta-cell dysfunction is the key component of hyperglycaemia in the aetiology of DM2. Research has been done on beta-cell function in subgroups with impaired glucose regulation or in small (ethnic) cohorts of the general population, but little is known about (determinants of) beta-cell function in the general adult population, assessed with a large cohort study.
Mental well-being
The prevalence of depression is twice as high in individuals with DM2 than in those without, but the causes of the high prevalence of depression in DM2 are unclear. Depression and other mental well-being related aspects (anxiety, mood disorders, somatisation) are indicators of stress. The evidence suggesting a relationship between psychosocial stress and the pathophysiology of glucose

intolerance and CVD is accumulating. A possible mechanism is the disturbance of the autonomic nervous system balance, but more research is needed to establish this.

Study objective

A. To determine prevalence and determinants of impaired glucose regulation
1. To study the prevalence of impaired glucose regulation and type 2 diabetes in the general population aged 40 to 65 years, and to compare these prevalence rates with those in the first Hoorn Study (1).
2. To study differences in various anthropometric and metabolic population characteristics (with special attention to lifestyle factors and body composition) between subgroups with a different glucose status.
3. To study differences in various indicators of cardiovascular disease (i.e. intima media thickness (IMT), cardiovascular risk profile, microalbuminuria, insulin resistance, hyperinsulinemia) between subgroups with a different glucose status.

B. To study beta-cell function in the general population
4. To study the distribution of insulin secretion and insulin sensitivity, as assessed by modelling of glucose and insulin concentration during a 75 g OGTT in the general population.
5. To study the (cross-sectional) association of various anthropometric and metabolic characteristics with beta-cell function in the general population.

C. To study mood disorders in subgroups with a different glucose status
6. To study the (cross-sectional) association between mood disorders and glucose status.
7. To study the role of autonomic nervous system balance in the association between mood disorders and glucose status.

Study design

The study is designed as a observational cohort in the general population.
A random sample of 5000 men and women, aged 40-65, will be drawn from the municipal registry of Hoorn, in order to include 3000 individuals (expected 60% inclusion rate).
The subjects will be invited in sub cohorts based on postal code (district) and will be asked to bring two visits to the Diabetes Research Center in Hoorn. The first visit is a relatively short visit aiming to include as many participants as possible in the study, after which a second (longer) visit will be scheduled. Following Dutch privacy legislation, all subjects are written on behalf of the municipality, with a description of the study, and the request to return a form with their name, address and telephone number (appendix 1). When subjects do not return the form within two weeks, a reminder will be sent (appendix 2).

After receiving the form, the investigators can contact the participants to check the exclusion criteria and schedule an appointment. The appointment made by telephone will be confirmed with a letter in which date and time and instructions to follow prior to visit 1 will be mentioned (appendix 3).
When all participants have visited the Diabetes Research Center for visit 1, appointments will be scheduled for visit 2. Time between visit 1 and 2 is expected to be about one year.
Subjects may withdraw at any time from the study without providing a reason.

Participants will bring two visit to the Diabetes Research Center in a fasting state

Visit 1
In- and exclusion criteria will be checked and informed consent will be obtained. Anthropometry (height, weight, waist circumference and hip circumference) and blood pressure measurement will be performed.
A 2-point Oral Glucose Tolerance Test (OGTT) , with blood draws at 0 en 120 minutes after glucose ingestion will be performed. Blood samples of both time points will be used for determination of glucose.
Habitual physical activity (SQUASH), food consumption (Voedselvragenlijst, Universiteit Wageningen), smoking, alcohol intake, employment, education, marital status, current medication use, disease history, family history of disease, depression (CES-D), anxiety (HADS), perceived general health (SF-12), and self-reported birth weight will be determined using questionnaires.

Visit 2
To estimate beta-cell function, a 7-point OGTT will be performed. Two fasting blood samples will be taken before the OGTT (t=-15 and 0), afterwards blood samples will be taken at 15, 30, 60 and 120 minutes. Blood samples of all time points will be used for determination of C-peptide, insulin and glucose. In addition, from the fasting blood sample, high sensitive CRP (CRP-hs, marker for low-grade inflammation), triglycerides, and total and HDL-cholesterol (markers for lipid metabolism) will be determined.
The standard 12-lead electrocardiogram will be recorded and the ankle-brachial index and carotid intima media thickness (IMT) will be determined as measures of prevalent cardiovascular disease. Measurements of heart rate variability will be made to estimate autonomic nervous system balance.
A sample of first void morning urine is requested for determination of microalbuminuria, as a marker for endothelial function (cardiovascular risk).

Study burden and risks

Patients need to visit the Diabetes Research Center in Hoorn twice in a fasting state. The first visit will take about 2,5 hours, the second visit about 5 hours.

There are 3 aspects to this protocol that may cause some discomfort to the subjects. First, the subjects have to abstain from heavy physical activities (e.g. sports) 48-h prior to the visits and remain fasted as indicated. Second, subjects may suffer from an unpleasant feeling of nausea during the OGTT (this might happen in about 1 in 60 people). This reaction should subside within 15 minutes to 1 hour. Third, the collection of blood may cause some discomfort. Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.
Benefits are that we will be albe to detect diabetes in an early stage, which gives the oppertunity for early treatment.

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

age 40-65 years

Exclusion criteria

malignant disease in the past 12 months, serious mental impairement (preventing to understand the study protocol), no understanding of the Ducht language and/or ability to fill out questionnaires properly

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-07-2006
Enrollment:	3000
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	NL12456.029.06