Follow-up New Hoorn Study - Diabetes research on patient stratification: glycaemic deterioration.

Published: 14-12-2012
Last updated: 01-05-2024

(1) To investigate the rate of glycaemic deterioration in subjects at high-risk of type 2 diabetes and with clinically manifest diabetes.(2) To identify biomarkers that define sub-classes of diabetes and thus enable targeted diabetes prevention or…

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

Summary

ID

NL-OMON41479

Source
ToetsingOnline

Brief title
Follow-up NHS - DIRECT: glycaemic deterioration.

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: Europese Unie: Innovative Medicines Initiative (IMI)

Intervention

Keyword: Biomarkers, Glycaemic deterioration, Pre-diabetes, Type 2 diabetes

Outcome measures

Primary outcome

The main study parameter is the rate of glycaemic deterioration in people with

type 2 diabetes and in people at high risk for type 2 diabetes, identifying

fast and slow deteriorators.

Secondary outcome

Not applicable.

Study description

Background summary

The phenotype of people who develop diabetes is highly variable, as is the rate at which their subsequent diabetes progresses, how they respond to diabetes therapy and who develops micro- and macrovascular complications. This heterogeneity forms a major barrier to effective patient management at the individual level. Type 2 diabetes is typified by a progressive deterioration in glycaemic control with time. A reliable biomarker that can be used to predict the trajectory of future glycaemic progression would help to identify subtypes of diabetes and in particular could help to inform individualised therapeutic selection and management.

Study objective

(1) To investigate the rate of glycaemic deterioration in subjects at high-risk of type 2 diabetes and with clinically manifest diabetes.

(2) To identify biomarkers that define sub-classes of diabetes and thus enable targeted diabetes prevention or treatment by identifying therapeutic targets that are more prevalent in some subgroups of the studied population.

Study design

A prospective cohort study, with extensive follow-up examinations for 2

subgroups. 500 subjects at high-risk of type 2 diabetes will be participating in study 1 and 167 subjects who are already diagnosed with type 2 diabetes will be participating in study 2.

Study burden and risks

For the study, 1 to 5 visits to the DOC VUmc will take a total of 3 to 15 hours.

On the day of the visit the subjects are required to attend fasting since 22.00. During the visits the participants are asked to fill in some questionnaires regarding medical history, quality of life, diet, physical activity, sleeping behaviour and a screening for diastolic heartfailure. In addition a physical examination including a sudoscan, anthropometry (height, weight, waist / thigh / hip / calf circumference, blood pressure, % body fat), blood collection and (in some of the subjects) a MRI scan will be performed. Participants will undergo a mixed meal tolerance test or a glucose tolerance test and toenail clipping. The subjects will also be asked to wear an accelerometer for 10 days. Prior to the visit, participants are asked to provide an urine and faecal sample.

Each visit a total amount of 10 to 79 ml blood will be collected. Blood withdrawal can cause discomfort and can result in bruising that continues up to a few days after the examinations. The glucose tolerance tests can lead to nausea and vomiting. By participating in the study, new data on the health of the subject can be detected (e.g. MRI).

In relation to the likelihood of injury, the severity of that injury and the vulnerability of the participants we concluded that performing the current research will result in a negligible risk for the participants and is therefore justified.

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

All surviving subjects who participated in 2006 - 2008 in the New Hoorn Study, since 2003/2004 in the RISC study or in 2005 - 2006 in the Hoorn meal study will be invited for this study.;Additional recruitment of subjects diagnosed with type 2 diabetes (to reach targets for DIRECT Study 2): patients diagnosed with type 2 diabetes for > 3 months and < 24 months, management by lifestyle with or without metformin therapy, HbA1c < 7.6% within previous 3 months, white European, age > 35 and < 75y and eGFR > 50ml/min.;Participants also have to speak, read and write Dutch to participate.

Exclusion criteria

Overall: Inability to give written informed consent (for instance due to dementia).;Study 1 and 2: pregnancy, lactation or a female planning to conceive within the study period, any significant medical reason for exclusion as determined by the investigator, unable to give written informed consent, unable to speak, read and/or write Dutch.;Study 1: Diabetes of any type, treatment with insulin sensitizing, glucose lowering, or other anti-diabetic drugs, HbA1c > 6,5%.;Study 2: type 1 diabetes, a previous HbA1c > 9.0%, prior treatment with insulin or an OHA other than metformin, BMI < 20 or > 50 kg/m2.

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):	15-03-2013
Enrollment:	2467
Type:	Actual

Ethics review

Approved WMO

Date:	14-12-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	16-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	18-08-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	15-12-2015
Application type:	Amendment
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	NL40099.029.12