Biobank 3 Hoorn Diabetes Care System Cohort follow up 2023

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To identify novel (causal) risk factors, including biomarkers and genetic determinants for disease progression and (severe) diabetes complications in people with T2D, in order to develop new, more targeted and effective therapies that will improve...

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

Summary

ID

NL-OMON53604

Source
ToetsingOnline

Brief title
BB3

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Sleep disturbances (incl subtypes)
- Vascular hypertensive disorders

Synonym
Diabetes, insulin insensitivity

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: NWO;EU

Intervention

Keyword: Biobank, Biomarkers, Complications, Diabetes

Outcome measures

Primary outcome

The primary endpoint are diabetes progression and incident diabetes complications, including microvascular complications (foot complications, retinopathy, nephropathy), macrovascular complications (cardiovascular disease, including myocardial infarction, angina pectoris, heart failure, stroke, transient ischaemic attack and peripheral arterial disease) as well as all-cause and cause-specific mortality.

Secondary outcome

Secondary endpoints include diabetes progression measured as anthropometrics, metabolic status, prevalence and severity of non-alcoholic fatty liver disease (NAFLD), medication use, psychological complications and quality of life.

Study description

Background summary

The morbidity and mortality risk of people with Type 2 diabetes (T2D) is twice as high compared to persons with normal glucose tolerance. Currently, despite treatment, clinical targets for cardiovascular risk factors are not achieved. The Hoorn Diabetes Care System cohort (DCS) is a prospective cohort representing a comprehensive dataset on the natural course of T2D. The cohort consists of persons with T2D in primary care from the West-Friesland region of the Netherlands. Enrolment in the cohort started in 1998 and this prospective dynamic cohort currently holds >15.000 persons with T2D. In subgroups of the cohort, biobanking and additional measurements have been performed to obtain information on, for example, lifestyle, depression and genetics. The current DCS biobank has contributed substantially to knowledge on determinants for diabetes complications in people with T2D, including for example magnesium.

Metabolic risk factors of interest are however time dependent and are influenced by treatment regimens, ageing and lifestyle. Because of recent changes in the treatment of diabetes including a larger range of oral hypoglycemic agents [2], to extent the current DCS biobank population sample and to obtain follow up samples from participants, a new biobanking effort is needed.

Study objective

To identify novel (causal) risk factors, including biomarkers and genetic determinants for disease progression and (severe) diabetes complications in people with T2D, in order to develop new, more targeted and effective therapies that will improve care and reduce the burden of T2D, by extension of our biobank.

Study design

Observational study

Study burden and risks

The time investments of the participants will be 1 hour and 15 minutes for one visit to the research centre or a home visit. The visit will be combined with a regular care visit, where possible, or otherwise scheduled separately from care. The burden is limited, but includes the vena puncture that can cause discomfort and can result in bruising that continues up to a few days after the examinations.
In relation to the possibility of damage, the severity of potential harm and the vulnerability of the participants it is concluded that the conduct of the research involves a negligible risk to human 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 adult newly diagnosed patients with T2D in the Hoorn DCS, who have not yet been asked to participate in research;
- All DCS participants with T2D who have previously provided informed consent to be contacted for research.

Exclusion criteria

• Unable to give written informed consent.
• Serious mental impairment i.e. preventing to understand the study protocol / aim.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-01-2024
Enrollment:	2500
Type:	Actual

Ethics review

Approved WMO

Date:	21-06-2023
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
ISRCTN	ISRCTN26257579
CCMO	NL82907.018.23