Determinants of long-term diabetes without complications: exploratory study of successful aging in patients with .+ 35 years T1 diabetes duration, or with autonomic neuropathy

Published: 08-11-2017
Last updated: 19-07-2024

Objective: To collect a broad array of clinical, behavioural, physical and biochemical parameters, to ensure that many clinical research questions or problems related to successful aging with T1D can be answered. Nevertheless, we have a priori...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON55768

Source
ToetsingOnline

Brief title
Determinants of long-term diabetes without complications

Condition

- Cardiac disorders, signs and symptoms NEC
- Diabetic complications
- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
type 1 diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Diabetesfonds Nederland

Intervention

Keyword: Biomarkers, Complications, Genetics, Type 1 diabetes

Outcome measures

Primary outcome

Main study parameters/endpoints:

Materials to be collected in addition for this project:

- extensive clinical evaluation of long-term glycaemic control, diabetes

treatment, (history of) hypoglycaemia, clinical complications, including

ophthalmologic examinations, hospital admissions, and -if present-

auto-antibody status at diagnosis. Sources will be digital records and letter

to GP*s.

- questionnaires related to medical history including (previous) smoking

status, previous surgery, family history, education, socio-economic situation,

work, sport and leisure time activities, peer support, well-being,

health-related quality of life, anxiety and depression, chronic fatigue.

- (preferably) fasting blood draw for collection of:

blood (serum, plasma)

buffy coat for isolation of DNA (Illumina GSA beadchip, Illumina 440k

methylation chip)

RNA / gene expression

- 2-hour post-breakfast urine collection.

- available routine laboratory measurements from the previous 5 years

(including haematology, HbA1c, liver enzymes, renal function, thyroid function,

vitamins (incl. vitD and vitB12) and antibodies, as well as auto-antibodies at

diagnosis).

- AGE-reader measurements (AGE-reader)

- picture of hands and feet

Secondary outcome

None

Study description

Background summary

Rationale:
Successful and healthy ageing, in particular in people with T1D is related to the propensity to be able to avoid secondary complications. There are two important types of complications that differ in their way to impact the quality of life:
a. microalbuminuria, high blood pressure, smoking, retinopathy and dysglycaemia all are related to the development of vascular complications such as myocardial infarction and stroke. For this reason, these complications are addressed in the yearly check-up of diabetes health, and treated - if appropriate - with ACE-inhibitors (microalbuminuria), blood pressure lowering agents in general, lifestyle interventions, and statins (in case of hyperlipidaemia).
b. autonomic neuropathy appears to be a separate type of long-term complications, and only very few risk factors for the development of AN have been identified until now (19). In the yearly diabetes evaluation this is a partly neglected complication. However, clinical evaluation of this type of complications is warranted. Autonomic neuropathy is associated with many complaints, severe fluctuations in glycaemic control, and a poor prognosis.

Study objective

Objective:
To collect a broad array of clinical, behavioural, physical and biochemical

parameters, to ensure that many clinical research questions or problems related to successful aging with T1D can be answered. Nevertheless, we have a priori postulated several research hypotheses, which we intend to solve with the available data:
1. People with type 1 diabetes of >= 35 years* duration, who are clinically free of complications, exhibit in contrast to subjects with clinically relevant manifestations:
a. a larger degree of residual beta-cell function as evidenced by higher urinary C-peptide secretion.
b. more beneficial biomarker composition of inflammatory, metabolic and genetic biomarkers.
c. lower degree of genome-wide DNA methylation of genes thought to be relevant for the development of inflammation and oxidative damage.
2. T1D subjects with clinically relevant manifestations of gastro-intestinal and/or cardiovascular autonomic neuropathy exhibit in contrast to T1D subjects clinically free of complications :
a. severe fluctuations of overall glycaemia.
b. reduced health-related quality of life, and impairments in daily life and work.
c. specific alterations in the profiles of gastro-intestinal hormones, and specific low-prevalence mutations in their genes and/ or their receptors.

Study design

Study design:
Cohort study

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Single visit to research center.
Extensive questionnaires.
Venipuncture and 56 ml of blood draw.
Follow-up questionnaires by mail and/or digitally.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. T1D determined by either autoantibodies or based on clinical and historical data or both, with a disease duration of at least 35 years.
2. T1D with established diabetic autonomic neuropathy, evidenced by delayed gastric emptying and / or cardiovascular autonomic neuropathy, irrespective of diabetes duration.
3. Treated for T1D at any center in The Netherlands.
4. Subject has been able to read the patient information sheet, understands the study protocol and agrees to comply with it, had time to ask questions and get answers, and were willing to give signed informed consent.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Non-T1D.
2. Patients with a duration of T1D less than 35 years and without AN
3. On experimental medication or participating in other studies with conflicting goals and schedules

4. Diseases or conditions that the investigator/physician believes to be a contraindication to participate.
5. Unwilling to be informed on incidental findings.

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):	01-11-2019
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO Date:	08-11-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-09-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-05-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	

Date:	06-07-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-01-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL62401.042.17