DIAbetes and LifEstyle Cohort Twente

Published: 31-05-2016
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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON53048

Source
ToetsingOnline

Brief title
DIALECT

Condition

- Coronary artery disorders
- Diabetic complications
- Nephropathies

Synonym
Diabetes, Type 2 Diabetes Mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente
Source(s) of monetary or material Support: NWO EDIC: exceptional and deep intelligent coach,Astra Zeneca,Eigen middelen. Daarnaast ad hoe subsidies per wetenschappelijke vraagstelling; te venwerven bij instanties zoals bedrijven of collectebusfondsen

Intervention

Keyword: diabetic complications, dietary habits, lifestyle, Type 2 diabetes mellitus

Outcome measures

Primary outcome

As different research questions will be formulated regarding our main

objective, different endpoints will be investigated such as:

• Blood pressure

• Renal function represented by creatinine clearance (calculated from 24h urine

creatinine excretion and plasma creatinine concentration)

• Occurrence of micro- and macrovascular complications

• Glucose variability determined by continuous glucose monitoring

Secondary outcome

Not applicable

Study description

Background summary

Type 2 diabetes mellitus (T2DM) is a highly prevalent disease, causing significant morbidity and mortality worldwide. Poor regulation of serum glucose can lead to debilitating micro- and macrovascular complications such as nephropathy, cardiovascular disease and amputations. Therefore preventing complications is an important treatment goal in T2DM. While numerous research is done on the effect of drug interventions, little is known about the effect of lifestyle and dietary habits. In this research we will focus on the effects of lifestyle and dietary habits on outcomes in T2DM.

Study objective

The primary objective of this study is to investigate the effect of lifestyle and dietary habits on outcomes in patients with type 2 diabetes mellitus.

Study design

The study is designed as an observational epidemiological study.
Cross-sectional and prospective analyses will be performed in a cohort with patients with diabetes.

Study burden and risks

There are no direct benefits for the patients to be included. Participation in the study is on a free-will base. Patients will not receive any financial support orpriority for treatment of other diseases in the clinic during this study. Patients will be asked to fill in questionnaires concerning their dietary intake, lifestyles, quality of life and beliefs on medication. 24-hour urine have to be collected by the patients, as well as a single portion of morning void urine. During their visit, blood pressure, weight, height, waist and hip circumference, physical condition, body impedance and peripheral polyneuropathy will be assessed. Blood samples will be drawn using venipuncture. Samples of the 24h urine, morning void urine and blood will be stored in -80°C according to the UMCG biobank regulations. No further invasive measurements will be executed and therefore risks of participation in this study are minimal, if present at all.

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

• Patients with type 2 diabetes mellitus
• Patients aged 18 years or older

Exclusion criteria

• Dependence on renal dialysis
• Severe general diseases or mental disorders making the participation in the study impossible
• Drug abuse (w/hich will be assessed through anamnesis)
• Not able to give written informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-11-2016
Enrollment:	850

Type:	Actual

Ethics review

Approved WMO Date:	31-05-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-10-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-04-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-05-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-02-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-10-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-11-2022
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-12-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-07-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23767
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL57219.044.16