DIALECT, "DIAbetes and LifEstyle Cohort Twente"

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23767

Source
NTR

Brief title
DIALECT

Health condition

Type 2 Diabetes Mellitus

Sponsors and support

Primary sponsor: Dr. G.D. Laverman
Internal medicine/nephrology
ZGT Hospital
Source(s) of monetary or material Support: Dr. G.D. Laverman
Internal medicine/nephrology
ZGT Hospital

Intervention

Outcome measures

Primary outcome

• All-cause mortality

• Macrovascular disease:

o coronary disease: myocardial infarction, silent myocardial infarction, hospital admission for unstable angina pectoris or heart failure, coronary artery bypass graft, percutaneous coronary intervention

o other: transient ischemic attack, cerebrovascular accident, diagnosis of peripheral vascular disease, peripheral bypass, percutaneous transluminal angioplasty, foot ulcers, amputation

• Microvascular disease: diagnosis of diabetic retinopathy, diabetic neuropathy, nephropathy

• Renal complications: nephropathy*, doubling of serum creatinine, start of renal replacement therapy

Secondary outcome

- blood pressure

- kidney function

- albuninurie

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.

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 population: The study population will consist of adult male and female patients with type 2 diabetes.

Intervention (if applicable):

Not applicable

Main study parameters/endpoints:

As dDifferent research questions will be formulated regarding our main objective.

Endpoints are, different endpoints will be investigated such as:

• All-cause mortality

• Macrovascular disease:

o coronary disease: myocardial infarction, silent myocardial infarction, hospital admission for unstable angina pectoris or heart failure, coronary artery bypass graft, percutaneous coronary intervention

o other: transient ischemic attack, cerebrovascular accident, diagnosis of peripheral vascular disease, peripheral bypass, percutaneous transluminal angioplasty, foot ulcers, amputation

• Microvascular disease: diagnosis of diabetic retinopathy, diabetic neuropathy, nephropathy

• Renal complications: nephropathy*, doubling of serum creatinine, start of renal replacement therapy

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

- Every year in december the outcome measures will be collected from the electronic file

from the general practitinor

- one baseline visit at the start of the trial to the clinic

Intervention

NONE

Contacts

Public
ZGT Almelo

G.D. Laverman
Zilvermeeuw 1

Almelo 7600SZ
The Netherlands
Tel: 088-7083079
Scientific
ZGT Almelo

G.D. Laverman
Zilvermeeuw 1

Almelo 7600SZ
The Netherlands
Tel: 088-7083079

Eligibility criteria

Inclusion criteria

• Male and female patients with type 2 diabetes

• Patients aged 18 years or older

• Follow-up taking place in the outpatient clinic internal medicine in the ZGT Hospital

• Written informed consent

Exclusion criteria

• Dependence on renal dialysis

• Severe general diseases or mental disorders making the participation in the study impossible

• Drug abuse (which will be assessed through anamnesis)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-08-2009
Enrollment:	850
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-04-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 53048
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5702
NTR-old	NTR5855
CCMO	NL57219.044.16
OMON	NL-OMON53048

Study results