

DIALECT, "DIAbetes and LiFestyle Cohort Twente"

Gepubliceerd: 19-04-2016 Laatste bijgewerkt: 15-05-2024

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23767

Bron

NTR

Verkorte titel

DIALECT

Aandoening

Type 2 Diabetes Mellitus

Ondersteuning

Primaire sponsor: Dr. G.D. Laverman

Internal medicine/nephrology

ZGT Hospital

Overige ondersteuning: Dr. G.D. Laverman

Internal medicine/nephrology

ZGT Hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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

Toelichting onderzoek

Achtergrond van het onderzoek

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 different 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

Doel van het onderzoek

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.

Onderzoeksopzet

- Every year in december the outcome measures will be collected from the electronic file from the general practitioner
- one baseline visit at the start of the trial to the clinic

Onderzoeksproduct en/of interventie

NONE

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	31-08-2009
Aantal proefpersonen:	850
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	19-04-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 53048

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten