

A population-based diabetes cohort: the Hoorn Diabetes Care System cohort

Submission date 15/12/2016	Recruitment status Recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 06/01/2017	Overall study status Ongoing	☐ Statistical analysis plan
		☐ Results
Last Edited 04/01/2017	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Diabetes is a lifelong condition that causes a person's blood sugar level to become too high. Previous studies have shown that people with type 2 diabetes are at increased risk of complications and mortality (death) compared to people without type 2 diabetes. Despite treatment, people with type 2 diabetes have higher levels of cardiovascular (heart disease) risk factors, such as high blood pressure, cholesterol and glucose levels. Diabetes care in the Netherlands was in need of improvement. For this reason, in 1996 centrally organised diabetes care was started in the region West-Friesland, a semi-urban region with 200,000 inhabitants and representative for a Western-European population, resulting in the Hoorn Diabetes Care System cohort (DCS). The DCS centre is responsible for the quality of type 2 diabetes care and uses managed care plans, working with contracted general practitioners (GPs). The managed care plan encompasses the care provided by a person's GP, according to the Dutch College of GPs' treatment guidelines for type 2 diabetes, and a standardised annual assessment organised centrally by the DCS centre. All people with type 2 diabetes in the region are included in the DCS cohort, which provides a unique opportunity for research.

Who can participate?

All people (all ages) with type 2 diabetes living in the West-Friesland region of the Netherlands

What does the study involve?

People with type 2 diabetes visit the DCS centre as part of the routine diabetes care. During this annual measurement, blood samples are taken to look at diabetes-related risk factors, blood pressure is measured and participants are asked about their smoking, medication use and other diseases. Anonymised electronic records are kept of these annual measurements and the participants are informed about the use of these records for research purposes. For specific research projects, in addition to the routine measurements, people are approached individually. When participants agreed to participate, additional questionnaires are filled in by the patients, or extra blood or urine samples are taken, depending on the type of the specific study.

What are the possible benefits and risks of participating?

Participants visit a specialized diabetes care center and their care is strictly monitored. Participation does not involve any extra risk compared to usual diabetes care.

Where is the study run from?

1. Diabetes Zorgsysteem locatie Hoorn (Netherlands)
2. Diabetes Zorgsysteem locatie Enkhuizen (Netherlands)
3. Diabetes Zorgsysteem locatie Hoogwoud/Opmeer (Netherlands)
4. Diabetes Zorgsysteem locatie Medemblik (Netherlands)
5. Diabetes Zorgsysteem locatie Slootdorp (Netherlands)
6. Diabetes Zorgsysteem locatie Wervershoof (Netherlands)
7. Diabetes Zorgsysteem locatie Venhuizen (Netherlands)

When is the study starting and how long is it expected to run for?

March 1996 to January 2030

Who is funding the study?

1. VU University Medical Center (Netherlands)
2. Dutch Federation of University Medical Centres (Netherlands)
3. Health insurers (Netherlands)
4. Netherlands Organisation for Scientific Research (Netherlands)
5. Netherlands Organisation for Health Research and Development (Netherlands)
6. Dutch Diabetes Foundation (Netherlands)
7. European Foundation for the Study of Diabetes (Germany)
8. International Diabetes Federation (Belgium)
9. European Innovative Medicine Initiative (Belgium)
10. European Union (Belgium)

Who is the main contact?

1. Dr Petra Elders (p.elders@vumc.nl)
2. Prof. Giel Nijpels (g.nijpels@vumc.nl)
3. Dr Amber van der Heijden (a.vanderheijden@vumc.nl)

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Type(s)

Scientific

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Additional identifiers**Protocol serial number**

1

Study information**Scientific Title**

The Hoorn Diabetes Care System cohort (DCS): an observational prospective cohort study

Acronym

DCS

Study objectives

People with type 2 diabetes (T2D) have a doubled morbidity and mortality risk compared to persons with normal glucose tolerance. Despite treatment, target values for cardiovascular risk factors are not achieved. The Hoorn Diabetes Care System cohort (DCS) study is a prospective longitudinal cohort study representing a complete dataset on the natural course of T2D, with repeated clinical measures and outcomes during follow-up.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Review Committee of the VU University Medical Center Amsterdam, 09/07/2009, ref: NL27783.029.09

Primary study design

Observational

Study design

Observational prospective cohort study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type 2 diabetes

Interventions

The DCS cohort study is an observational study and no specific intervention of treatment is performed.

All people with type 2 diabetes from all the 103 general practitioners in the West-Friesland region of the Netherlands are included in the cohort. In this prospective cohort study, examination of persons with type 2 diabetes of the DCS cohort is performed annually and include measurement of, among others, all diabetes-related risk factors and medication use. Microvascular complications are assessed by measuring kidney function, and screening feet and eyes. Information on cardiovascular disease is obtained by self-report, electrocardiography and electronic patient registrations.

In subgroups of the cohort, biobanking and additional measurements were performed to obtain information on, for example lifestyle, depression, and genomics. Finally, the cohort is linked to data on registrations on cancer and all-cause mortality.

Intervention Type

Other

Primary outcome(s)

1. Microvascular complications, measured annually:

- 1.1. Nephropathy: urinary albumin-creatinine ratio (mg/mmol), from an overnight first-voided urine sample
- 1.2. Kidney function estimated according to the Modification of Diet in Renal Disease (MDRD) formula. Microalbuminuria was defined as urinary albumin-creatinine ratio >2.0 mg/mmol
- 1.3. Retinopathy, measured by fundus photography of both eyes. All photographs were graded according to the EURODIAB classification score: grade 0: "no retinopathy," grade 1: "minimal non-proliferative retinopathy," grade 2: "moderate non-proliferative retinopathy," grade 3: "severe non-proliferative or pre-proliferative retinopathy," grade 4: "photocoagulated retinopathy," and grade 5: "proliferative retinopathy"
- 1.4. Diabetic foot, determined by dermatologic and musculoskeletal inspection; check for skin pressure and foot deformity; neurological assessment including test of protective sensation using a 10-g monofilament and test of vibratory sensation using a 128-Hz tuning fork; assessing presence of peripheral arterial disease (PAD) by foot pulses; and assessing presence of limited joint mobility. Complications of the foot are categorized according to the classification system of the International Working Group on the Diabetic Foot: 0: no neuropathy, 1: neuropathy, 2: neuropathy and deformity or PAD, 3: history of foot ulceration or a lower-extremity amputation

2. Cardiovascular complications, measured by:

- 2.1. Self-reported events during the annual visit

2.2. Electrical conduction system, a standard resting 12-lead electrocardiogram coded according to the Minnesota coding, measured annually.

2.3. Electronic patient registration from the regional hospital and GP, updated every three years. In this morbidity and mortality registration, cardiovascular diseases are coded according to the International Classification of Diseases, Injuries and Causes of Death, ninth revision, including ICD-9 codes 390 to 459, and 798

3. Cancer: via linkage with information on cancer morbidity which was obtained from the nationwide Netherlands Cancer Registry. Topography and morphology are coded according to the International Classification of Diseases for Oncology (ICDO). Data on primary treatment, chemoradiation, radiotherapy, hormone therapy and surgery have been included

4. Mortality: checked every six months using the National population registry and cause of death determined using GP records and coded as explained above using the morbidity and mortality registry. Cause of death is coded according to the ICD-9

Key secondary outcome(s)

Quality of life and physical functioning, assessed by self-reported questionnaires at a single timepoint in 2006

Completion date

01/01/2030

Eligibility

Key inclusion criteria

All people (all ages) with type 2 diabetes living in the West-Friesland region of the Netherlands

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

All

Sex

All

Key exclusion criteria

No exclusions

Date of first enrolment

01/10/1996

Date of final enrolment

01/01/2030

Locations

Countries of recruitment

Netherlands

Study participating centre**Diabetes Zorgsysteem locatie Hoorn**

Maelsonstraat 7

Hoorn

Netherlands

1624 NP

Study participating centre**Diabetes Zorgsysteem locatie Enkhuizen**

Molenweg 7b

Enkhuizen

Netherlands

1601 SR

Study participating centre**Diabetes Zorgsysteem locatie Hoogwoud/Opmeer**

Raadhuisstraat 5

Hoogwoud

Netherlands

1718 BM

Study participating centre**Diabetes Zorgsysteem locatie Medemblik**

Compagniesingel 7

Medemblik

Netherlands

1671 KC

Study participating centre**Diabetes Zorgsysteem locatie Slootdorp**

Brink 53

Slootdorp

Netherlands

1774 BB

Study participating centre

Diabetes Zorgsysteem locatie Wervershoof
Olympiaweg 141
Wervershoof
Netherlands
1693EK

Study participating centre
Diabetes Zorgsysteem locatie Venhuizen
Twijver 66a
Venhuizen
Netherlands
1602BW

Sponsor information

Organisation
VU University Medical Centre

ROR
<https://ror.org/00q6h8f30>

Funder(s)

Funder type
University/education

Funder Name
VU University Medical Center

Funder Name
Dutch Federation of University Medical Centres

Funder Name
Health insurers

Funder Name

Nederlandse Organisatie voor Wetenschappelijk Onderzoek

Alternative Name(s)

Netherlands Organisation for Scientific Research, Dutch National Scientific Foundation, Dutch National Science Foundation, Dutch Research Council (Nederlandse Organisatie voor Wetenschappelijk Onderzoek), NWO:Nederlandse Organisatie voor Wetenschappelijk Onderzoek, Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO), Dutch Research Council, The Dutch Research Council (NWO), Dutch Research Council, Netherlands, NWO

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Netherlands

Funder Name

ZonMw

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Funder Name

Dutch Diabetes Foundation

Funder Name

European Foundation for the Study of Diabetes

Alternative Name(s)

The European Association for the Study of Diabetes, European Association for the Study of Diabetes (EASD), EFSD

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Germany

Funder Name

International Diabetes Federation

Funder Name

European Innovative Medicine Initiative

Funder Name

European Union

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Petra Elders (p.elders@vumc.nl).

IPD sharing plan summary

Available on request