# Study on the prevalence and determinants of glucose intolerance in a Dutch caucasian population: the Hoorn Study

| Submission date   | Recruitment status                | <ul><li>Prospectively registered</li></ul> |
|-------------------|-----------------------------------|--|
| 16/12/2016        | No longer recruiting              | ☐ Protocol                                 |
| Registration date | Overall study status              | Statistical analysis plan                  |
| 03/04/2017        | Ongoing                           | ☐ Results                                  |
| Last Edited       | Condition category                | Individual participant data                |
| 20/06/2025        | Nutritional, Metabolic, Endocrine | [X] Record updated in last year            |

#### Plain English summary of protocol

Background and study aims

Type 2 diabetes is a chronic (long-term) disorder where blood glucose (sugar) levels are too high. The prevalence of type 2 diabetes is increasing worldwide, bringing a high risk of complications of the eyes, kidneys and foot, and cardiovascular (heart) diseases. Many risk factors for diabetes have been identified. However, many factors are involved in type 2 diabetes and questions remain on interactions between risk factors. The aim of this study is to assess the prevalence and risk factors of impaired glucose metabolism (a pre-diabetic state) and diabetes in the general population.

Who can participate?

Men and women aged 50–75 randomly selected from the municipal registry in the year 1989

What does the study involve?

The participants visit the centre six times over 25 years to provide blood and urine samples, to be tested for diabetes, to be measured, and to complete questionnaires. Participants are followed up using the municipality register to check for the occurrence of chronic diseases.

What are the possible benefits and risks of participating?

There is minimal risk of participating, except for some bruising from blood drawn.

Where is the study run from?

Diabetes Zorgsysteem locatie Hoorn (Netherlands)

When is the study starting and how long is it expected to run for? January 1989 to January 2080

Who is funding the study?

- 1. VU University Medical Center of Amsterdam
- 2. Nederlandse Organisatie voor Wetenschappelijk Onderzoek
- 3. ZonMw

- 4. European Union
- 5. Novartis Pharma
- 6. Diabetes Fonds
- 7. Netherlands Heart Foundation

Who is the main contact?

- 1. Prof Dr Joline Beulens
- J.beulens@amsterdamumc.nl
- 2. Dr Femke Rutters

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# Contact information

#### Type(s)

Scientific

#### Contact name

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# Additional identifiers

#### **EudraCT/CTIS** number

Nil known

#### IRAS number

#### ClinicalTrials.gov number

Nil known

#### Secondary identifying numbers

Nil known

# Study information

#### Scientific Title

Prospective observational study on the prevalence and determinants of glucose intolerance in a Dutch caucasian population: the Hoorn Study

#### Acronym

Hoorn study

#### **Study objectives**

The Hoorn study was initiated to study the prevalence and risk factors of impaired glucose metabolism and diabetes in an elderly Caucasian population. This initially cross-sectional study has been extended to a prospective cohort over the past decades, to study the risk factors for disturbances in glucose metabolism and complications associated with disturbances in glucose metabolism.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics Review Committee of the VU University Medical Center Amsterdam, 27/06/1989, ref: 89 /092

#### Study design

Prospective observational study with five follow-up visits during a 25-year period, and ongoing registry of morbidity and mortality

#### Primary study design

Observational

#### Secondary study design

Longitudinal study

# Study setting(s)

Community

#### Study type(s)

Other

#### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

# Health condition(s) or problem(s) studied

Impaired glucose metabolism and type 2 diabetes

#### **Interventions**

Between the years 1989 and 1992, a population-based survey of glucose tolerance was performed in the Dutch city of Hoorn in the West-Friesland region of the Netherlands. During this baseline measurement, information was obtained on, among others, glucose metabolism, diabetes-related risk factor levels and complaints, lifestyle, dietary intake, and demographic variables.

Physical re-examinations, repeating the measurements at baseline with additional extensive measurement to assess diabetes complications, were conducted in 1990-1991, 1996-1998, 2000-2001, 2005-2007, and 2007-2009.

All visits have corresponding measurements, including glucose metabolism determined by fasting plasma glucose, 75-g Oral Glucose Tolerance Test and HbA1c; anthropometrics; blood plasma lipid levels; albumin/creatinine ratio; blood pressure; family history of diabetes, self-reported medication use, disease history, diabetes-related complaints, lifestyle determinants and socio-economic status.

Finally, in addition to physical follow-up visits, all participants are still actively followed up for vital status by linkage with the municipality register and for occurrence of cardiovascular disease, cancer and cause-specific mortality, by checking their medical records.

In subsamples of the cohort, extensive physical diabetes complications have been measured, such as a retinopathy screening, autonomic function tests, peripheral neuropathy, ankle-arm pressure-ratio, echo-doppler scanning van de carotis and electrocardiography. In all visits additional measurements have been conducted, which vary from visit to visit.

#### Intervention Type

Other

#### Primary outcome measure

Disturbances in glucose metabolism, measured by fasting plasma glucose, 75-g Oral Glucose Tolerance Test and HbA1c at baseline and at the two follow-up measurements in 2010-2011 and 2013-2015

#### Secondary outcome measures

- 1. Depressive symptoms, measured using CES-D questionnaire at baseline and 7 year follow up
- 2. Quality of life, measured using questionnaires at baseline and 7 year follow up
- 3. Cardiovascular complications of diabetes, measured by a check of the medical records of the participants every 3 years

# Overall study start date

01/01/1989

#### Completion date

01/01/2080

# **Eligibility**

#### Key inclusion criteria

- 1. Men and women
- 2. Aged 50-75 years
- 3. Randomly selected from the municipal registry

#### Participant type(s)

All

#### Age group

Senior

#### Sex

Both

#### Target number of participants

2484

#### Key exclusion criteria

Participants with a non-Caucasian background

#### Date of first enrolment

01/01/1989

#### Date of final enrolment

12/12/1992

# Locations

#### Countries of recruitment

Netherlands

# Study participating centre Diabetes Zorgsysteem locatie Hoorn

Maelsonstraat 7 Hoorn Netherlands 1624 NP

# Sponsor information

#### Organisation

VU University Medical Center of Amsterdam

#### Sponsor details

De Boelelaan 1089a Amsterdam Netherlands 1081 HV +31 (0)20 444 5860 J.beulens@amsterdamumc.nl

#### Sponsor type

University/education

#### **ROR**

https://ror.org/00q6h8f30

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

Amsterdam University Medical Centers

#### Alternative Name(s)

Amsterdam UMC, Amsterdam University Medical Centres, AUMC

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

Universities (academic only)

#### Location

Netherlands

#### **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, 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

European Union

#### **Funder Name**

Novartis Pharma

#### Alternative Name(s)

Novartis Deutschland GmbH, Novartis Pharma GmbH, Novartis Deutschland

#### Funding Body Type

Private sector organisation

#### Funding Body Subtype

For-profit companies (industry)

#### Location

Germany

#### Funder Name

Diabetes Fonds

#### Alternative Name(s)

**Dutch Diabetes Research Foundation** 

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

#### Location

Netherlands

#### Funder Name

Netherlands Heart Foundation

# **Results and Publications**

#### Publication and dissemination plan

Publications in high-impact peer reviewed journals

#### Intention to publish date

01/01/2081

#### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Joline Beulens (J.beulens@amsterdamumc.nl)

#### IPD sharing plan summary

Available on request