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The New Hoorn Study

Submission date 22/12/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 24/03/2017	**Overall study status** Ongoing	
Last Edited 20/06/2025	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Current plain English summary as of 26/04/2022:

Background and study aims:
Type 2 diabetes mellitus (T2DM) is a long term condition where a person is unable to control their blood sugar (glucose) levels as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). T2DM is a multi-factorial disease, meaning that it is associated with the effects of multiple genes in combination with lifestyle and environmental factors. The aim of this study is to look at the prevalence (commoness) and risk factors of impaired glucose metabolism (sugar breakdown) and diabetes in the general population.

Who can participate?
Men and women, aged between 40 and 65 years, registered at the municipal population registry of Hoorn.

What does the study involve?
In the year 2006, participants are asked to join the cohort (collection of participants). In the past 15 years, they visit the study centre four times, whilst being actively followed up for vital status by linking with the municipality register and for occurrence of long-term diseases. When they visit the centre, participants have a number of blood and urine samples taken to assess their blood sugar control, are weighted and measured, and fill out several questionnaires.

What are the possible benefits and risks of participating?
There are no notable benefits of participating. There is a small risk of pain and bruising following blood tests.

Where is the study run from?
The Diabetes Care and research Center in Hoorn (Netherlands)

When is study starting and how long is it expected to run for?
January 2006 to January 2080

Who is funding the study?
Amsterdam UMC, VU University Medical Center (Netherlands)

Who is the main contact?
1. Prof Joline Beulens (scientific)
j.beulens@amsterdamumc.nl
2. Dr Femke Rutters (scientific)
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Previous plain English summary:

Background and study aims:
Type 2 diabetes mellitus (T2DM) is a long term condition where a person is unable to control their blood sugar (glucose) levels as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). T2DM is a multi-factorial disease, meaning that it is associated with the effects of multiple genes in combination with lifestyle and environmental factors. The aim of this study is to look at the prevalence (commoness) and risk factors of impaired glucose metabolism (sugar breakdown) and diabetes in the general population.

Who can participate?
Men and women, aged between 40 and 65 years, registered at the municipal population registry of Hoorn.

What does the study involve?
In the year 2006, participants are asked to join the cohort (collection of participants). In the past 10 years, they visit the study centre three times, whilst being actively followed up for vital status by linking with the municipality register and for occurrence of long-term diseases. When they visit the centre, participants have a number of blood and urine samples taken to assess their blood sugar control, are weighted and measured, and fill out several questionnaires.

What are the possible benefits and risks of participating?
There are no notable benefits of participating. There is a small risk of pain and bruising following blood tests.

Where is the study run from?
The Diabetes Care and research Center in Hoorn (Netherlands)

When is study starting and how long is it expected to run for?
January 2006 to January 2050

Who is funding the study?
VU University Medical Center (Netherlands)

Who is the main contact?
1. Dr Joline Beulens (scientific)
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Study website
https://hoornstudies.com/

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
A population-based study on glucose tolerance: the New Hoorn Study

Acronym

Hoorn study

Study objectives
The aim of this study is to investigate whether the increasing rates of longevity, physical inactivity and obesity affected the prevalence and risk factors of disturbances in glucose metabolism.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/05/2006, Medical Ethics Committee of the VU University Medical Center Amsterdam (de boelelaan 7, Amsterdam, 6200 MD, Netherlands; -; metc@amsterdamumc.nl), ref: 2006/93

Study design
Observational prospective cohort study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Current interventions as of 26/04/2022:

Participants are enrolled from the Hoorn study, a population-based survey carried out in the city of Hoorn between 2006-2007. The first visit takes place in 2006-2007. In a subgroup, around 250 participants a follow up visit takes place after three years. The third and fourth visit take place 8 and 15 years after baseline in the entire cohort.

For each visit, participants are requested to refrain from eating and drinking (except water) from 8:00 P.M. the night before the visit and from drinking alcohol from 5:00 P.M. the day before the visit. They are instructed to follow their usual diet the day before each visit and to be consistent in their diet (both in content and in approximate timing of evening meals and snacks) and physical activities on the pre-visit days. In addition, participants are requested not to smoke on the morning of the visit and not to come by bicycle. Participants do not follow these instructions will be asked to reschedule the visit. Upon arrival at the Diabetes Research Center, written

informed consent is obtained. During the visit, height and weight are measured without shoes and heavy clothes. Waist circumference, hip circumference and blood pressure is measured. Fasting whole blood glucose from a capillary vein in the finger was determined on the spot. In participants with a fasting whole blood glucose level <10 mmol/l, a standard 75-g OGTT is performed. Venous blood samples are drawn before and 120 min after glucose ingestion. Finally, participants fill out questionnaires on lifestyle, medication, disease and SES. During the visit three years after baseline, microvascular function will be determined using capillary videomicroscopy of the dorsal skin of the nail fold.

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Previous interventions:

Participants are enrolled from the Hoorn study, a population-based survey carried out in the city of Hoorn between 2006-2007. The first visit takes place in 2006-2007. In a subgroup, around 250 participants a follow up visit takes place after three years. The third visit takes place 8 years after baseline in the entire cohort.

For each visit, participants are requested to refrain from eating and drinking (except water) from 8:00 P.M. the night before the visit and from drinking alcohol from 5:00 P.M. the day before the visit. They are instructed to follow their usual diet the day before each visit and to be consistent in their diet (both in content and in approximate timing of evening meals and snacks) and physical activities on the pre-visit days. In addition, participants are requested not to smoke on the morning of the visit and not to come by bicycle. Participants do not follow these instructions will be asked to reschedule the visit. Upon arrival at the Diabetes Research Center, written informed consent is obtained. During the visit, height and weight are measured without shoes and heavy clothes. Waist circumference, hip circumference and blood pressure is measured. Fasting whole blood glucose from a capillary vein in the finger was determined on the spot. In participants with a fasting whole blood glucose level <10 mmol/l, a standard 75-g OGTT is performed. Venous blood samples are drawn before and 120 min after glucose ingestion. Finally, participants fill out questionnaires on lifestyle, medication, disease and SES. During the visit three years after baseline, microvascular function will be determined using capillary videomicroscopy of the dorsal skin of the nail fold.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 26/04/2022:

Disturbances in glucose metabolism is measured by fasting plasma glucose, 75-g Oral Glucose Tolerance Test and HbA1c at baseline and at the three follow-up measurements in 2010-2011 and 2013-2015 and 2021-2023.

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Previous primary outcome measure:

Disturbances in glucose metabolism is 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 are measured using CES-D questionnaire at baseline and 7 year follow up
2. Quality of life is measured using questionnaires at baseline and 7 year follow up
3. Cardiovascular complications of diabetes are measured by a check of the medical records of the participants every three years

Overall study start date
01/12/2005

Completion date
01/01/2080

Eligibility

Key inclusion criteria
1. Men and women
2. Aged 40-65 years
3. From the municipal registry in the city of Hoorn

Participant type(s)
All

Age group
Adult

Sex
Both

Target number of participants
2807

Key exclusion criteria
No exclusion criteria

Date of first enrolment
13/07/2006

Date of final enrolment
01/11/2007

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

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Sponsor type
University/education

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
VU University Medical Center of Amsterdam

Funder Name
Novartis Pharma B.V

Funder Name
the European Union

Funder Name
the Innovative Medicine Initiative

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/01/2080

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