ISRCTN37454880 https://doi.org/10.1186/ISRCTN37454880

The Diabetes Pearl: diabetes biobanking in the Netherlands

Submission date	Recruitment status	[_] Prospectively registered
16/12/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/01/2017	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/01/2017	Nutritional, Metabolic, Endocrine	[_] 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. Patients with type 2 diabetes have a high risk of cardiovascular (heart) disease and other complications which reduce their quality of life and require high levels of healthcare. The aim of this study is to examine the risk factors for diabetes complications, including biomarkers (molecules that can be measured in blood or tissue) and genetic information.

Who can participate?
Patients with type 2 diabetes in the Netherlands

What does the study involve?
Participants are asked permission to use their medical data for scientific research. The following information is collected: personal information, medication use, physical examination (body measurements, blood pressure, electrocardiography [heart electrical activity], retina [eye] photographs, vibration perception), questionnaires (socio-economic status, lifestyle, [family] history of disease, and well-being), and laboratory measurements. Participants also contribute urine and blood samples and DNA for genetic analysis. National databases like the municipality register are used for mortality (death rate) follow-up.

What are the possible benefits and risks of participating?
There is no direct benefit for the participants. In the future, the study results may lead to improvements in diabetes care. There are no risks of participating.

Where is the study run from?
VU University Medical Center (Netherlands)

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

Who is funding the study?
1. Dutch Ministry of Health, Welfare and Sport (Netherlands)
2. Dutch University Hospitals (Netherlands)

Who is the main contact?
Dr Petra Elders

Study website
http://parelsnoer.org/page/nl/

Contact information

Type(s)
Scientific

Contact name
Dr Petra Elders

Contact details
Department of General Practice and Elderly Care
EMGO Institute for Health and Care Research
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1081 BT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
The Diabetes Pearl: diabetes biobanking in the Netherlands - an observational prospective cohort study

Study objectives
Type 2 diabetes is associated with considerable comorbidity and severe complications, which reduce quality of life of the patients and require high levels of healthcare. The Diabetes Pearl is a large cohort of patients diagnosed with type 2 diabetes, covering different geographical areas in the Netherlands. The aim of this study is to create a research infrastructure that will allow the study of risk factors, including biomarkers and genetic determinants for severe diabetes complications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the VU University Medical Center, 09/07/2009, ref: NL27783.029.09

Study design
Observational prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

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
Type 2 diabetes

Interventions
Baseline examinations were performed November 2009 - November 2016. To ensure quality of the data collected, standard operation procedures were developed and used in all 8 recruitment centers. From all patients who provide informed consent, the following information is collected: personal information, medication use, physical examination (antropometry, blood pressure, electrocardiography (ECG), retina photographs, ankle-brachial index, peripheral vibration perception), self-report questionnaire (socio-economic status, lifestyle, (family) history of disease, and psychosocial well-being), laboratory measurements (glucose, A1c, lipid profile, kidney function), biobank material (storage of urine and blood samples and isolated DNA). Follow-up of morbidity and mortality is planned through medical care providers and municipal registries. All gathered clinical data and biobank information is uploaded to a database for storage on a national level. Biobanks are maintained locally at all recruitment centers.

Intervention Type
Other

Primary outcome measure
Diabetes complications and mortality:
1. Cardio-metabolic risk factors, assessed by anthropometry, blood pressure, ECG, ankle-brachial index, laboratory measurements, and self-report questionnaire at baseline
2. Retinopathy, assessed by retinal photography at baseline
3. Nephropathy, assessed with laboratory measurements at baseline
4. Neuropathy, assessed by peripheral vibration perception at baseline
Follow-up visits have not been planned yet. Follow-up of morbidity and mortality is done through medical care providers and municipal registries.

Secondary outcome measures
Quality of life and physical functioning, assessed by self-reported questionnaire at baseline

Overall study start date
02/11/2006

Completion date
01/01/2050

Eligibility

Key inclusion criteria
1. Patients with type 2 diabetes mellitus according to WHO criteria
2. Treated by a Dutch University Clinic, an associated primary care clinic or transmural care system

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
7000

Key exclusion criteria
None

Date of first enrolment
01/11/2009

Date of final enrolment
01/11/2016

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Center
Amsterdam
Netherlands
1081 HV

Sponsor information

Organisation
VU Universtity Medical Center

Sponsor details
De Boelelaan 1089a
Amsterdam
Netherlands
1081 BT

Sponsor type
University/education

Website
http://parelsnoer.org/page/nl/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Government

Funder Name
Ministerie van Volksgezondheid, Welzijn en Sport

Alternative Name(s)
Dutch Ministry of Health, Welfare and Sport, VWS

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Netherlands

Funder Name
Dutch University Hospitals

Results and Publications

Publication and dissemination plan
The first results are expected in 2017.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
Data will not be made available. Proposals for collaborative research can be submitted to Dr Petra Elders.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/11/2012		Yes	No