String of Pearls - Diabetes Cohort: Generation of a Dutch academic Bio-Databank for the study of the etiology of type 2 diabetes mellitus and related diseases and complications

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON44892

Source
ToetsingOnline

Brief title
String of Pearls - Diabetes Cohort

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Diabetic complications

Synonym
Diabetes Mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diabetes Mellitus, Epidemiology

Outcome measures

Primary outcome

The associations of demographic, clinical, biochemical and genetic risk markers

factoren with diabetes complications.

Secondary outcome

na

Study description

Background summary

In 2007 the prevalence of type 2 diabetes in The Netherlands, based of GP registries is 3,5%, and 14% for those over 65 years old. Due to the increasing numbers of elderly people and the inreased prevalence of overweight and obesity, the prevalence and the costs of type 2 diabetes will increase dramatically in the near future. Treatment and care of diabetes complication such as kidney failure, heart failure, and foot ulcers will be a growing burden on the health care system, since duration of diabetes is the strongest risk factor for diabetes complications and diabetes now occurs at younger ages. Prevention of diabetes complications by the identification of modifyable risk factors and better treatment strategies is the only way to control the costs. Because complications such as kidney failure and ampuations of the lower extremities occur relatively infrequent, large-scale studies are required to assess the risk factors.

Study objective

The goal of the *String-of-Pearls national academic biobank - the diabetes cohort* is to create a nation diabetes bio-databank, with DNA, urine and blood samples of 12.000 diabetespatients in combination with clinical data from the

diabetes care in order to:
1. identify (genetic) risk markers for uncontroled diabetes and (cardiovascular) diabetes complications,
2. evaluate the (cost-) effectiveness of therapies/medication,
3. provide descriptive statistics.

Study design

The Diabetes Pearl will first perform a baseline examination. The goal for the future is to perform annual follow-up of cause-specific mortality, cardiovascular events, and other diabetes complications. Preferably an annual standardised medical examination will be performed to assess risk factors, medication and (cardiovascular) complications.
In order to achive these goals, the 8 Dutch University medical center have agreed on standardised measurements, blood and urine sampling, assessing a minimal dataset and management of the bio-databank.

The minimal dataset:
1. Personal information (data for local use by care provider only) ID, name and adress, gender, date of birth, general practitioner, pharmacist. date consultation, etnicity, type of informed consent, date informed consent.
2 Biomaterials:
- fasting blood sampling (plasma, serum, DNA) Direct measurement of: glucose, creatinin, total cholesterol, HDL cholesterol, triglycerides, HbA1c.
- Urine sample first void. Direct measurement of: dipstick leukocytes, dipstick nitrite, creatinine and albumine.
3. Clinical examination:
- Medication
- ECG
- Ophthalmology
4. Physical examination:
- Antropometry
- Blood pressure
5. Questionniares:
- demography, smoking, alchohol consumption, medical history, family history
- Rose questionnaire (self report of AP, MI, stroke, claudication)
- EQ5D (quality of life)

Study burden and risks

Participants will give addtional blood and urine samples for the biobank when attending the clinical for the diabetes care visit. They will be requested to fill out a questionnaire (duration ~ 30 min). In addition consent will be asked for access to their personal and medical data at their GP, pharmacy, hospital, the Central Bureau of Statistics and the Municipal Regsitry.

Contacts

Public
Vrije Universiteit Medisch Centrum

van der Boechorststraat 7
Amsterdam 1081 BT
NL
Scientific
Vrije Universiteit Medisch Centrum

van der Boechorststraat 7
Amsterdam 1081 BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Diagnsosis of type 2 diabetes mellitus according to the WHO 2006 criteria

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-10-2009
Enrollment:	12000
Type:	Actual

Ethics review

Approved WMO Date:	09-07-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-07-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-08-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL27783.029.09