A prospective cohort study in the development of type 2 diabetes and cardiovascular disease: The CODAM study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON37934

Source
ToetsingOnline

Brief title
The CODAM (Cohort on Diabetes and Atherosclerosis Maastricht) study

Condition

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

Synonym
diabetes and cardiovascular disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiovascular Disease, Cohort, Observational, Type 2 Diabetes Mellitus

Outcome measures

Primary outcome

(1) Development and progression of insulin resistance, glucose intolerance and

type 2 diabetes in the CODAM study population.

(2) Development and progression of atherosclerosis, vascular dysfunction and

CVD in the CODAM study population.

Specific outcomes:

- International Classification of Diseases version 10 (ICD-10 codes) :

E11 (type 2 diabetes)

I10-15 (hypertensive disease)

I20-25 (ischaemic heart disease)

- Subcutaneous and visceral fat

- Ectopic fat in the liver

- insulin resistance and glucose tolreance status

- Measures of arterial structure (including carotid Intima-Media-Thikcness &

Ankle-Brachial Index) and function (including arterial stiffness)

- Presence of Metabolic Syndrome (according to the most recent defintion of

Alberti et al (2009))

Secondary outcome

(1) Mortality

(2) Liver enzymes (reflecting progression of NAFLD).

(3) Adiposity (BMI, waist-to-hip ratio, waist circumference, skinfold thickness)

(4) Gene expression, biomarkers and/or genetic variations; differences between subjects with and whithout (incident) T2DM

(5) Gene expression, biomarkers and/or genetic variations;differences between subjects with and whithout (incident) CVD

Outcomes of the Maastriccht studie for as far as these are not included in the primary outomes of the CODAM study. The study can be described in term of study endpoints which are based upon on the International Classification of Diseases version 10 (ICD-10 codes) and include:

Diabetes, pre-diabetes and the metabolic syndrome

- Ectopic fat in the pancreas

Cardiovascular Imaging

- I42-44; I47-51 Other Forms of Heart Disease

- I26 Pulmonary Embolism

- I73.9; I79.2 Peripheral Artery Disease

- I80.1-3 Deep Venous Thrombosis

C: Neurological Diseases

- I61; 63; 64 Cerebrovascular Disease

- G43 Migraine

- F00-01 Dementia

- F32 Depression

- H90; 93.1 Diseases of the Ear

- H25; 28; 35.8; 36; 40; 54 Diseases of the Eye

- G99; 63.3 Neuropathy

- Cerebral small vessel disease

- Cerebral connectivity

D: Respiratory Diseases and other co-morbidities

- G47.3 Sleep Apnoea

- J41; 42; 44 Respiratory Disease

E: Lifestyle & Behavioural Studies

- M10 Gout

- S02; 12; 22; 32; 42; 52; 62; 72; 82; 92 Fractures

- T02; 08; 10; 12; 14.2; 93.2 Fractures

- M80-82; 84 Osteoporosis

- S91 Ulceration of the Foot or Ankle

Study description

Background summary

Despite progress in our understanding of the development of cardiometabolic diseases, including type 2 diabetes and cardiovascular disease, the exact genetic and metabolic background of the development of these diseases is still not known in detail. The Cohort study of Diabetes and Atherosclerosis (CODAM, initiated in 1999) is a prospective cohort study in the Netherlands aiming at the investigation of the effects of glucose metabolism and lipids, lifestyle and genetics on the development of cardiovascular disease and cardiovascular complications.

Study objective

In the current study we will re-examine the participants of the CODAM study in a second follow-up evaluation (12 yrs after baseline) in order to obtain further longitudinal information on the natural development of type 2 diabetes and cardiovascular disease in elderly subjects. This investigation will enrich and strengthen the scientific data obtained in the CODAM baseline (CODAM1; MEC 99-112) and first follow-up (CODAM2; MEC 05-170; 7 yrs after baseline) evaluations. Multiple follow-up measurements (i.e. at multiple time-points; as opposed to only one) will substantially improve our power to identify and validate the relevant novel risk markers and risk factors for these common and highly relevant disorders.

Study design

Observational, longitudinal, prospective cohort study

Study burden and risks

Participation involves three site visits, during which a detailed health check-up is conducted. The detailed assessmentof health status may reveal prevalent disease in a preclinical and/or asymptomatic stage. On the one hand awareness of normally unknown pathology may affect a person's perception of his own health negatively. On the other hand, early detection is likely to have favourable effects on disease progression and enable early intervention. Each participant will receive an individual lifestyle advice on how to improve his or her health.

Contacts

Public
Universiteit Maastricht

Universitetissingel 50
Maastricht 6229 ER
NL
Scientific
Universiteit Maastricht

Universitetissingel 50
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Partricipant in baseline measurement of the CODAM study (MEC99-112)

Exclusion criteria

None, except for limitations that interfere with any of the procedured to obtain informed consent according to the Helsinki declaration

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2013
Enrollment:	500
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-11-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL37680.068.12