

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

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Heart failures
<b>Study type</b>	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 tolerance status

- Measures of arterial structure (including carotid Intima-Media-Thickness & Ankle-Brachial Index) and function (including arterial stiffness)

- Presence of Metabolic Syndrome (according to the most recent definition 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 without (incident) T2DM
- (5) Gene expression, biomarkers and/or genetic variations; differences between subjects with and without (incident) CVD

Outcomes of the Maastricht studie for as far as these are not included in the primary outcomes of the CODAM study. The study can be described in terms of study endpoints which are based upon 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 assessment of 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**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

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

### Exclusion criteria

None, except for limitations that interfere with any of the procedures 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