The Maastricht Study

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

Summary

ID

NL-OMON34961

Source
ToetsingOnline

Brief title
The Maastricht Study

Condition

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

Synonym
type 2 diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Europese Unie;Provincie;Wijerhorst Stichting en MUMC zelf

Intervention

Keyword: epidemiology, Maastricht, population-based, type 2 diabetes

Outcome measures

Primary outcome

The covering structure of the Maastricht Study can then be described along 7 separate research lines that are highly interrelated:

A. Diabetes, pre-diabetes and the metabolic syndrome

Focus: the implementation of novel techniques to study glucose tolerance status / the metabolic syndrome in relation to the development of both micro- and macro cardiovascular disease.

B. Cardiovascular Imaging

Focus: the implementation of techniques to study structure and function of the central and peripheral circulation and, their relationship with any of the study endpoints

C. Neurological Diseases

Focus: the implementation of techniques to study structure and function of the central and peripheral nervous system and, their relationship with any of the study endpoints

D. Respiratory Diseases and other co-morbidities

Focus: the implementation of spirometry and ambulatory respiratory monitoring, gastro-intestinal disease and, their relationship with any of the study endpoints

E. Lifestyle & Behavioural Studies

Focus: the implementation of questionnaires and function tests that provide information about diet, exercise and illness behaviour / coping mechanisms in chronic disease and, their relationship with study endpoints (including muscular-skeletal diseases).

F. Public Health

Focus: the collection of demographic as well as socio-demographic data; in addition a repetitive morbidity and mortality surveillance will be held on all participants

G. Biomarker Collection & Biobanking

Focus: establishment of a biobank, which includes blood-, urine-, faeces- and DNA - sampling. In addition to the collection of microbial nasal swabs and respiratory air samples.

Endpoints & Determinants

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:

A: Diabetes, pre-diabetes and the metabolic syndrome

- E11 Type 2 Diabetes

- Subcutaneous and visceral fat

- Ectopic fat in liver and pancreas

B: Cardiovascular Imaging

- I10-15 Hypertensive Disease

- 20-25 Ischemic Heart Disease

- 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

Secondary outcome

not applicable (yet)

Study description

Background summary

In the Western world, the prevalence of obesity is increasing at an alarming rate. Consequently, the prevalence of the metabolic syndrome, type 2 diabetes and cardiovascular disease is increasing. A particular alarming phenomenon is that the occurrence of obesity shifts towards younger generations (<50 years) in an ageing population (currently 51% of the Dutch adult population is moderately to severely overweight (BMI >= 25 kg/m2). In addition, it has become increasingly clear that the presence of obesity not only precedes the development of the metabolic syndrome, type 2 diabetes and cardiovascular disease but also of many other chronic illnesses (such as osteoporosis, depression, dementia and chronic lung disease) and that particularly the presence of type 2 diabetes seems to accelerate the development of other chronic illnesses.

The above will most certainly have an important impact on society, future health care and the individual patient. Yet, the underlying pathophysiology of the above phenomena is only partially understood. It is therefore of paramount importance to come to a better understanding of the pathophysiology of obesity, the metabolic syndrome and type 2 diabetes in order to withstand the increasing demands of the obesity epidemic upon society.

Study objective

Aim of the Maastricht Study

The primary objectives of the Maastricht Study are:
1. to study the development of obesity, the metabolic syndrome and type 2 diabetes in the general population.
2. to study the development of cardiovascular disease in the general population and how diabetes and the metabolic syndrome accelerate this.
3. to study the clustering of other chronic diseases in the general population and
how diabetes and the metabolic syndrome accelerate this.
4. to identify novel biomarkers or risk factors in order to facilitate the identification of the high-risk patient which would benefit most from early intervention.

Study design

The Maastricht Study is closely intertwined with the Pearl String Initiative on Diabetes (het Parelsnoer Initiatief (*Diabetes Parel*); METC 09/107) and The Maastricht Study will act as covering structure. In short, the aim of the Pearl String Initiative on Diabetes (Appendix III) is to set up a nation-wide diabetes biobank of individuals with type 2 diabetes in order to identify risk markers for cardiovascular and diabetes-related complications and to evaluate the effectiveness of therapy and medication. The data set is oriented towards the prediction of cardiovascular morbidity and mortality (METC 09/107). The Maastricht Study will expand this initiative by additional phenotyping of all Pearl Sting Initiative participants (n = 3000), by sampling an additional cohort of 2000 Maastricht Study participants with type 2 diabetes and by sampling a cohort of 5000 Maastricht Study participants without type 2 diabetes (Figure 1). Of note: all Pearl String participants will be asked to give informed consent to participate in the Maastricht Study separately from the Pearl String Initiative.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participation involves four site visits, in which a detailed health check 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 condition 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 should be an inhabitant of Maastricht and Heuvelland region and between 40 to 75 years of age. Moreover, all participants need to have normal mental capacities and be legally not restricted in any way.
Addititional inclusion criteria for the diabetes subgroup are diagnosed type 2 diabetes

according to GP criteria or fasting circulating levels of glucose of 6.1 mmol/L or more or circulating levels of 10.0 mmol/L or more after 2-hours glucose load (oral glucose tolerance test).[33]

Exclusion criteria

None, except for nursing home residency, hospital or psychiatric institute admission and (severe) cognitive limitations which interferes 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:	Recruiting
Start date (anticipated):	02-11-2010
Enrollment:	10000
Type:	Actual

Ethics review

Approved WMO Date:	18-10-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-05-2011

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-10-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	15-05-2013
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC 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	NL31329.068.10