Netherlands Epidemiology of Obesity study

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Primary general objectives of the NEO study1. To study the pathways that lead to common diseases in overweight and obese individuals.2. To identify novel determinants of various diseases and conditions in overweight and obese individuals.3. To study...

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

Summary

ID

NL-OMON55863

Source
ToetsingOnline

Brief title
NEO Study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Lipid metabolism disorders
- Bronchial disorders (excl neoplasms)

Synonym
obesity-related diseases

Research involving
Human

Sponsors and support

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

Intervention

Keyword: epidemiology, etiology, morbidity, obesity

Outcome measures

Primary outcome

The occurence of clinical diseases and conditions during follow-up, e.g.

insulin resistance (impaired glucose tolerance and type 2 diabetes mellitus),

dyslipidemia, hypertension, clinical manifestations of atherosclerosis

including coronary artery disease, myocardial infarction, stroke, venous

thrombosis and pulmonary embolism, chronic obstructive pulmonary disease and

asthma, renal failure, osteoarthritis, rheumatoid arthritis, and mortality.

Secondary outcome

not applicable

Study description

Background summary

The prevalence of overweight and obesity has risen dramatically over the past decades.
Obesity has been associated with a range of diseases, most notably diabetes mellitus and cardiovascular disease, the number one cause of death in industrialised countries. These include myocardial infarction, ischemic stroke, peripheral artery disease, deep vein thrombosis and pulmonary embolism. In addition, obesity may lead to disabling disorders such as osteoarthritis and chronic obstructive pulmonary disease and asthma. Moreover, obesity is related to stress, anxiety and depression.
Insights into how obesity leads to disease are only just emerging. It has become clear that the adipocyte is not an inert storage unit of fat, but that this cell is highly active in controlling and signalling, both humoral and via the autonomic nervous system, thus affecting whole body metabolism. This led to the concept of toxic effects of adipose tissue.
The diseases that affect overweight and obese individuals are all common diseases that exact a heavy toll on society. Therefore, the study of the

occurrence of these diseases, the interplay between, and with, additional genetic and acquired risk factors, and the relation between the various disease outcomes, is relevant to obese and non-obese individuals alike. Performing a study among obese individuals may therefore be seen as the use of a model in which the incidence of disease is increased, and relations relevant to the aetiology and pathophysiology of the common diseases can be more readily studied.

Study objective

Primary general objectives of the NEO study

1. To study the pathways that lead to common diseases in overweight and obese individuals.
2. To identify novel determinants of various diseases and conditions in overweight and obese individuals.
3. To study interrelationships between diseases, newly identified determinants with each other and with classical,
established risk factors.

Secondary general objectives of the NEO Study

1. To identify novel determinants of various subclinical conditions in overweight and obese individuals.
2. To develop novel methods for determining the risk of various diseases and conditions in asymptomatic
overweight and obese individuals, in addition to established
prognostic markers.
3. To assess the burden of disease in a population-based cohort of overweight and obese individuals.
4. To investigate the optimal diagnostic method to define overweight and obesity in terms of predicting various
diseases.

Study design

The NEO study is a population-based, prospective cohort study.

Study burden and risks

The participants will complete multiple validated questionnaires, collect 24-hours or 12-hours urine, and undergo a series of measurements at the NEO study site. These include anthropometric assessments and blood pressure, body composition, blood sampling both fasting, and 30 minutes and 2.5 hours after a mixed meal, resting EKG, carotid artery IMT and distensibility, and pulmonary function tests. In a random subset of participants visceral fat, liver

triglyceride content, and pulse wave velocity of the aorta will be measured by MRI, or assessment of basal metabolic rate, extensive echocardiography, or a 5-day continuous recording of physical activity and heart rate (variability) with a
combined accelerometer and 2 ECG pads (ActiHeart).

Participants will receive the results of tests for which, according to national guidelines, testing is recommended (e.g. blood pressure, and levels of glucose, total and HDL-cholesterol, triglycerides, and renal function). Abnormal levels will be marked and will be accompanied by an advice to consult their general practitioner. Furthermore, any abnormal pulmonary function tests will be followed by an invitation for a more extensive pulmonary function test to identify chronic pulmonary obstructive disease or asthma. Abnormal results of the MRI scan that may have consequences for their health will be disclosed to the participants and their general practitioners. Results of other measurements will not be disclosed.

Participation in the NEO study in total takes at least 2 days (including completing the questionnaires and collection of 24-hours urine) to a maximum of 5 days (when the participant is assigned to Actiheart). The NEO study will produce a wealth of information allowing the study of possible causes of disease in overweight or obese individuals. Urine, blood and DNA will be stored in a biobank allowing future analyses of many new questions without new blood sampling necessary. Eventually the result may lead to future identification and treatment of high risk individuals.

For the second measurements the participants will complete multiple validated questionnaires, collect a morning spot urine, a feacal sample, and undergo a series of measurements at the NEO study site. These include anthropometric assessments and blood pressure, body composition, fasting blood sampling, carotid artery IMT, pulmonary function tests, a fibroscan and a pinpricktest. In random subsets of participants abdominal and liver fat, heart function or knee osteoarthritis will be measured by MRI, or bone density by DXA, or a hair sample will be taken, or physical activity will be measured during a week with a wrist-worn triaxial accelerometer (Actigraph).The second measurement will take in total 1 day with or without an extra appointment to undergo MRI scanning. Those participants with Actigraph will wear the watch for a week and return it to us in a supplied envelop.

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

- Age between 45 and 65 years
- BMI of at least 27 kg/m2

Exclusion criteria

- Severe psychiatric disease
- Life expectancy of less than 6 months
- Inability to read and understand Dutch language

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):	01-09-2008
Enrollment:	6000
Type:	Actual

Ethics review

Approved WMO Date:	04-08-2008
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	20-06-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-06-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-06-2020

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-04-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	31-01-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-07-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
ClinicalTrials.gov	NCT03410316
CCMO	NL21981.058.08