New Hoorn Study: *Cause and consequences of disturbed microcirculation: effects of glucose tolerance status*

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1. Do body fatness and/or body fat distribution show a linear association withmicrovascular function in normal as well as IGT subjects?2. Is the effect of body composition on the microvasculature mediated by alteredadipokine profile, low-grade...

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

Summary

ID

NL-OMON34753

Source
ToetsingOnline

Brief title
Effects of glucose tolerance on microvascular function

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Lipid metabolism disorders
- Vascular disorders NEC

Synonym
1. vascular dysfunction 2. pre diabetes related change in microvessels

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Aventis,Nederlandse Hart Stichting

Intervention

Keyword: cardiovascular diseases, glucose tolerance, microcirculation

Outcome measures

Primary outcome

microvascular function (structural by number of baseline capillaries and

functional by %recruitment after arterial occlusion using capillary microscopy)

Secondary outcome

early signs of atherosclerosis (by IMThickness and distensibility in the

carotis using ArtLab echografie)

markers of endothelial dysfunction and low grade inflammation (using blood

samples and elisa)

current glucose tolerance status starting with a one-touch glucose measurement

and 3 serum samples at start, afetr 1hr and after 2hrs (an OGTT)

Anthropometry: Length, weight and WHratio, skinfolds, whole-body DXA scan,

using standard techniques

Blood pressure, Systolic and diastolic pressures measured in triplicate in

sitting position using in the left upper arm at 5-minute intervals with an

oscillometric device

Questionnaires: Time/date of measurement, menses. current medication, SES, work

status, physical activity, smoking, alcohol, nutrition and mental well-being.

Study description

Background summary

A disturbed structure and function of the small vessels in the human body (i.e. the microcirculation: MC) plays an important role in the development of common cardiovascular diseases such as diabetes and hypertension. In the context of cardiovascular disease development, causes and consequences of microvascular dysfunction are relatively unknown. A plausible risk factor for microvascular dysfunction is overweight, but the underlying pathways remain unclear. Although, a contribution of microvascular dysfunction to the development of diabetes and hypertension is suggested in previous studies, these experimental studies are based on animal models and small human populations with extreme phenotypes.

Hypotheses of this study:
1. Overweight leads to microvascular dysfunction via markers of low grade inflammation (adipocytokines), endothelial dysfunction and disturbances in lipid profile.
2. Microvascular dysfunction leads to an elevated blood pressure and a decrease in insulin sensitivity.
3. Microvascular dysfunction is associated with early signs of atherosclerosis

The aforementioned relations will be tested in 200 apparently healthy subjects divided in 2 groups based on glucose tolerance status in 2006 (i.e. normal or impaired glucose tolerance). The structure and function of the MC will be examined in the nailfold, using videomicroscopy. The data obtained regarding structure and function of the MC can be related to body fatness, blood pressure, large artery properties and serum sample parameters to unravel underlying mechanisms. The proposed design is novel and allows to separate of culprit mechanisms. Results of this study can confirm theories and may improve prediction and prevention of cardiovascular diseases in the future.

Study objective

1. Do body fatness and/or body fat distribution show a linear association with

microvascular function in normal as well as IGT subjects?
2. Is the effect of body composition on the microvasculature mediated by altered adipokine profile, low-grade inflammation and /or markers of endothelial dysfunction?
3. Is microvascular dysfunction associated with reduced insulin sensitivity, higher
blood pressure and/or dyslipidemia?
4. Is microvascular dysfunction associated with accelerated subclinical atherosclerosis?
5. Is there a difference in microvascular function between normal and impaired glucose tolerant subjects, matched for age, sex and BMI?
6. Are the associations studied under research questions 2-4 different between NGT
and IGT subjects?

Study design

observational cohort study

Study burden and risks

Subjects are 43-68years and part of the original *New Hoorn* cohort as invited in 2006. In the previous round of measurement participants were asked whether they were willing to participate in and approved to be invited for follow-up measures. Each subject is asked for a complete morning including an OGTT, 4 venapunctions, a complete body scan, carotis scan using echografie, capillary microscopy video and anthropometry measurements. Completed with questionnaires on lifestyle, perceived health and well being.

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

participation in the last measure round of 2006 and written approval for contact in new measure rounds

Exclusion criteria

indication of diabetes (type I or II) and or diagnosed with malignant diseases last 12 months

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2010
Enrollment:	200

Type:	Actual

Ethics review

Approved WMO Date:	17-03-2010
Application type:	First submission
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	NL31152.029.10