

Predictors of Left Ventricular Deterioration in people with and without Type 2 Diabetes: The Hoorn Study

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1. To study the rate of change of diastolic and systolic LV function and LV structure, and the incidence of heart failure over a 7-year period in subjects with and without DM2 2. To study the potential determinants of accelerated deterioration of LV...

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

Summary

ID

NL-OMON30584

Source

ToetsingOnline

Brief title

LV Deterioration in people with and without DM2: The Hoorn Study

Condition

- Heart failures
- Diabetic complications
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

heart failure, left ventricle deterioration

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Diabetes Fonds

Intervention

Keyword: Diabetes Mellitus, Echocardiography, Heart Failure, Left Ventricular Function, type 2

Outcome measures

Primary outcome

The main study parameter is left ventricular deterioration, comparing left ventricular systolic and diastolic functioning in 2007-2008 with 2000-2001, measured by echocardiography.

Secondary outcome

Secondary study parameters are insulin resistance and/or metabolic syndrome, micro vascular angiopathie, arterial stiffness and endothelial dysfunction, and low grade inflammation.

Study description

Background summary

Patients with type 2 diabetes (DM2) have increased prevalence of Left Ventricular (LV) hypertrophy and symptomatic and asymptomatic LV dysfunction. In cross-sectional data from the Hoorn Study the increased LV mass in DM2 could not be explained by arterial stiffness or impaired flow mediated vasodilation, or traditional risk factors. In contrast to increased LV mass, of which less than 10% could be attributed to insulin and glucose levels, over 30% of the elevated prevalence of systolic and diastolic LV dysfunction was attributable to high levels of insulin and glucose.

This study will be the first population based prospective study with repeated echocardiographic examinations of LV structure and function. We hypothesise that progression of LV deterioration will be related to insulin resistance, metabolic syndrome, arterial stiffness, endothelial dysfunction, micro-vascular angiopathy, and low grade inflammation.

Study objective

1. To study the rate of change of diastolic and systolic LV function and LV structure, and the incidence of heart failure over a 7-year period in subjects with and without DM2
2. To study the potential determinants of accelerated deterioration of LV structure and function, focussing on:
 - insulin resistance and/or metabolic syndrome
 - micro vascular angiopathy
 - arterial stiffness and endothelial dysfunction
 - low grade inflammation

Study design

Cohort study.

Study burden and risks

- The subjects will have to visit the Diabetes Care and Research Centre Hoorn (DOC) 2 time for 6 hours total. Blood samples will be taken.
- The subjects are now 58-93 years old. Considering this age range the present project may place considerable burden on the subjects. For this reason the measures are clustered together to ensure that the subjects have to visit the DOC no more than 2 times and for a maximum of 4 hours per visit. All measurements will be performed by trained research assistants to make each visit as comfortable as possible.
- Subjects have to remain fasted at arriving for the visit. A total amount of 35 ml of blood will be withdrawn by means of vena puncture (and a capillary blood sample of the finger). This could cause a bruise.
- During echocardiographic measurements, the subject has to lie on his/her left side. Actual measurements will be done afterwards in digitally stored images, to limit the amount of time to a maximum of 30 minutes.
- During each vascular measurement, the subject has to stay in a fixed, immobilised position for a maximum of 10 min.
- When measuring blood pressure, the inflation of the cuff may cause transient paraesthesia in the hand.
- The OGTT could cause vomiting.
- Subjects have to fill in The Hoorn Study questionnaire (developed by the EMGO institute), the Diabetes Symptom Checklist 2, the LAPAQ, the IADL, the SF-12, and the CES-D.
- 6 electrodes will be placed on places surrounding the heart during the biometrical measurements for registration of heart rate variability.

Contacts

Public

Vrije Universiteit Medisch Centrum

van der Boechorststraat 7
1081 BT Amsterdam
Nederland

Scientific

Vrije Universiteit Medisch Centrum

van der Boechorststraat 7
1081 BT Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Surviving subjects who participated in relat-2 from the Hoorn Study in 2000-2001, of whom satisfactory echocardiograms could be made then, will be invited for this study.

Participants also have to speak, read and write Dutch to participate.

Exclusion criteria

If no echocardiogram could be made in 2000-2001, this subject will be excluded from this study.

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2007
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO	
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	NL15631.029.07