

# Early recognition of heart failure in patients with diabetes type 2 in primary care.

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Primary:- To assess the prevalence of (unrecognised) HF in primary care patients with diabetes type 2. - To establish the most cost-effective diagnostic strategy to recognise HF in these patients. Secondary:- To assess the impact of heart failure,...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Heart failures
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON32109

### Source

ToetsingOnline

### Brief title

Heart failure in diabetes (UHFO-DM)

### Condition

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

### Synonym

heart failure

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Ministerie van OC&W,Fonds Nuts Ohra

## Intervention

**Keyword:** diabetes, diagnosis, health related Quality of Life, heart failure

## Outcome measures

### Primary outcome

Prevalence (with exact 95% confidence intervals) of (unrecognised) heart failure (systolic and 'isolated' diastolic) and diagnostic value of signs and symptoms (including co-morbidity), NT-proBNP, ECG and a combination of these items. Moreover, the cost-effectiveness of the different diagnostic strategies.

### Secondary outcome

Impact of heart failure, and the combination of diagnosis and treatment of heart failure, on health related quality of life in patients with type 2 diabetes.

## Study description

### Background summary

We hypothesize that the prevalence of heart failure in patients with diabetes type 2 aged 60 years and over is relatively high (15% or more), that most of them will be unknown, and that a cost-effective strategy to detect unrecognised heart failure in these patients can be developed. The strategy is expected to include some signs and symptoms (such as laterally displaced apical beat), B-type natriuretic peptide measurements (Amino-terminal B-type natriuretic peptide (NT-proBNP)), and possibly electrocardiography. In a subset of patients straightforward echocardiography may prove to be cost-effective diagnostic screening strategy. With information from our study the detection of previously unknown heart failure in diabetes patients can be improved, enabling the physician to initiate beneficial morbidity and mortality reducing heart failure treatment more timely.

### Study objective

Primary:

- To assess the prevalence of (unrecognised) HF in primary care patients with diabetes type 2.
- To establish the most cost-effective diagnostic strategy to recognise HF in these patients.

Secondary:

- To assess the impact of heart failure, and the combination of diagnosis and treatment of heart failure, on health related quality of life of patients with diabetes type 2.

## **Study design**

A prospective diagnostic efficiency study

## **Study burden and risks**

With the answers to these questions, a substantial number of patients with diabetes type 2 and with previously unrecognised HF can be offered morbidity and mortality reducing treatment. The burden is a 1.5 hours lasting standardised diagnostic assessment with history taking, physical examination, electrocardiography, echocardiography, blood tests, and health related quality of life questionnaires. Patients will be asked if we can contact them afterwards for follow-up and for repeating the hRQoL questionnaires. During the diagnostic assessment we will only use established and safe investigations (electrocardiography and echocardiography).

## **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

- Patients (men or women) with diabetes type 2
- Enlisted with the diabetes service of the Diagnostic Center in Etten-Leur (SHL)
- Age 60 years or older

### Exclusion criteria

Those with a cardiologist-confirmed (and thus known with a) diagnosis of heart failure. The latter group will not be invited for the diagnostic assessment at the cardiology outpatient clinic, to prevent them from redundant investigations. Moreover, by adding up the prevalence of those already known with heart failure with the prevalence rate of newly detected (previously unknown) heart failure patients after the diagnostic assessment provides the overall prevalence of heart failure in patients with diabetes aged 60 years and over. Thus, the overall prevalence rate of heart failure (known plus newly detected) can be calculated without diagnostic assessment of those with diabetes already known with established heart failure. This group will be asked to answer the Quality of Life questionnaires.

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 07-02-2009  
Enrollment: 600  
Type: Actual

## Ethics review

Approved WMO  
Date: 02-12-2008  
Application type: First submission  
Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

## 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	NL22717.041.08