

# Evaluation of the prevalence of non-alcoholic fatty liver disease (and steatohepatitis) in patients with type 2 diabetes mellitus

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Evaluation of the incidence of liver enzyme abnormalities and hepatic steatosis in all type 2 diabetes mellitus patients (about n=1500) treated at the outpatient clinic internal medicine of the St Lucas Andreas Hospital

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Diabetic complications
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON29718

### Source

ToetsingOnline

### Brief title

Prevalence of NAFLD in type 2 DM

### Condition

- Diabetic complications
- Gastrointestinal inflammatory conditions
- Lipid metabolism disorders

### Synonym

fatty liver, NASH

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

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

## Intervention

**Keyword:** diabetes mellitus, NAFLD, steatohepatitis, steatosis

## Outcome measures

### Primary outcome

Disturbed liver enzymes (i.e. AP, gammaGt, ASAT and ALAT)

Increased hepatic echogenicity (hepatic steatosis)

### Secondary outcome

not applicable

## Study description

### Background summary

The consequence of an increasing prevalence of obesity and type 2 diabetes mellitus (DM2) is an increase in patients with hepatic steatosis (HS). 80-90% patients of DM2 suffers from HS of which 20% finally develops steatohepatitis and eventually livercirrhosis. Little is known about the precise incidence. Pathophysiologically, a two-hit theory is proposed. Insulin resistance leading to hepatic lipid accumulation is the first hit. Subsequently oxidative stress with formation of oxygen species and lipid peroxidation contributes to a second hit. The AMC in collaboration with the VUMC developed an outpatient clinic for patients suffering from NASH. Research aims are the development of non-invasive diagnostic procedures and in the (near) future therapeutic interventions. Besides these aims, the exact incidence of NASH and DM2 is relevant. Early detection of HS and the resulting medical intervention will lead to an improvement of the metabolic syndrome.

### Study objective

Evaluation of the incidence of liver enzyme abnormalities and hepatic steatosis in all type 2 diabetes mellitus patients (about n=1500) treated at the

## Study design

A single venous blood sample (10 cc) is taken during standard blood sampling (standard care). Liver enzymes will be measured (alanine aminotransferases (ALAT), asparagin aminotransferases (ASAT), gamma-glutamyl-transferases (\*Gt), alkaline phosphatase (AP), bilirubin and lactate dehydrogenase (LDH). Clinical data are collected, specifically diabetic complications and other liver diseases.

If any liver enzyme abnormality then further analysis will be performed:

- repeat liver enzymes, if again abnormal then;

serology of viral hepatitis (HBsAg and anti-HCV)

auto-immune serology (ANA, anti-SMA)

abdominal ultrasound

sampling of one extra tube (10 cc): storage of plasma and buffy coat

- when negative analysis and on ultrasound only hepatic steatosis patient will be asked to participate in the outpatient clinic NASH at AMC or VUMC

## Study burden and risks

Single venous blood sampling (10 cc)

## Contacts

### Public

Vrije Universiteit Medisch Centrum

De Boelelaan 1117  
1081 HV Amsterdam  
Nederland

### Scientific

Vrije Universiteit Medisch Centrum

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1081 HV Amsterdam  
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## Trial sites

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

All type 2 diabetes mellitus patients visiting the outpatient clinic internal medicine of the Sint Lucas Andreas Hospital Amsterdam

## Exclusion criteria

none

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-05-2006

Enrollment: 1500

Type: Anticipated

## Ethics review

Approved WMO

Date: 19-07-2006

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	NL11695.029.06