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

Ethical review	Approved WMO
Status	Pending
Health condition type	Diabetic complications
Study type	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

outpatient clinic internal medicine of the St Lucas Andreas Hospital

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

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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