Validation of quantitative hepatic fat ultrasonography, by means of a MRI technique.

Published: 25-01-2007
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The aim of this study is to validate a protocol for ultrasonographic hepatic fat assessment, by means of Magnetic Resonance Imaging technique (MRI) as gold standard.

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

Summary

ID

NL-OMON30811

Source
ToetsingOnline

Brief title
Validation of ultrasonographic hepatic fat assessment.

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Hepatic and hepatobiliary disorders
- Lipid metabolism disorders

Synonym
Fatty Liver Disease (FLD)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hepatic lipids, MRI, Ultrasonography

Outcome measures

Primary outcome

Amount of liver fat: pixel intensity (mode, mean, sd) for ultrasonography and

peak areas (H2O : fat) for MRI.

Secondary outcome

Body mass index, waist circumference, blood pressure.

Study description

Background summary

Cardiovascular disease is primary dead cause number 1 in the western population, making studies on early risk factors mandatory. Several studies suggest that the amount of liver fat may be a predictor for future cardiovascular disease. Ultrasonography is an attractive technique for performing large epidemiologic field studies.

Study objective

The aim of this study is to validate a protocol for ultrasonographic hepatic fat assessment, by means of Magnetic Resonance Imaging technique (MRI) as gold standard.

Study design

Validation study

Study burden and risks

Burden: Non-invasive ultrasonography, lying motionless for a long time (40 min) with noise in the MRI scanner.

Risks: Small

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

Differences with other participants: a study population as heterogenous as possible. However, this does not guarantee large difference in the amount of liver fat.

Exclusion criteria

viral hepatitis, cirrosis

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2007
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	25-01-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL15584.042.06