Non-invasive quantification of liver fibrosis with ultrasound: pilot

Published: 04-05-2012
Last updated: 01-05-2024

Main goal: In this non-invasive pilot study, we want to investigate whether these techniques can discriminate between healthy livers and livers with cirrhosis. For the new techniques to be applied as an alternative for biopsy, the output values of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational non invasive

Summary

ID

NL-OMON37760

Source
ToetsingOnline

Brief title
Non-invasive quantification of liver fibrosis

Condition

- Hepatic and hepatobiliary disorders

Synonym
liver fibrosis, liver scarring

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: elastography, liver fibrosis, ultrasound

Outcome measures

Primary outcome

The main study outcomes are:

• Reference intervals

• Intra- and interobserver variability

To this end, the following variables will be measured / calculated: strain (for elastography) and inhomogeneity (for ASQ), their variances, the corresponding effect size and coefficients of agreement.

Secondary outcome

nvt

Study description

Background summary

There is an urgent need for reliable non-invasive methods to evaluate the degree of liver fibrosis. The current gold standard, liver biopsy, has several disadvantages such as a high sampling variability and a high morbidity. Ultrasound offers two techniques that might be sensitive enough to quantify liver fibrosis. In this pilot study, we want to measure normal and extreme values in healthy and diseased livers.

Study objective

Main goal: In this non-invasive pilot study, we want to investigate whether these techniques can discriminate between healthy livers and livers with cirrhosis. For the new techniques to be applied as an alternative for biopsy, the output values of patients with livers with cirrhosis should minimally overlap with those of persons with healthy livers. Moreover, intra- and interobserver variations should be low.

Study design

All subjects undergo an ultrasound examination which comprises the two new techniques.
In group 1, each exam consists of four repeated observations by two observers according to Obs1-Obs2-Obs1-Obs2

Study burden and risks

Ultrasound is a very safe technique that does not use ionizing radiation. The examinations, which require placing a probe on the skin between ribs under mild pressure, is rarely experienced as unpleasant

Contacts

Public
Universitair Medisch Centrum Groningen

Postbus 30.001
9700 RB Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Postbus 30.001
9700 RB Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Group 1: 25 healthy volunteers, age 25-70 years, BMI 20-40
Group 2: 25 patients with histologically confirmed cirrhosis, age > 18 years

Exclusion criteria

Group 1
History of liver disease
Excessive alcohol use (> 25 consumptions per week for men, > 10 consumptions per week for women)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-05-2012
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	04-05-2012
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	NL38429.042.11