The effect of a standardized amount of fat on the CAP-value for non-invasively measuring liver fat content.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23759

Source
NTR

Brief title
CAPtivating

Health condition

Non-alcoholic fatty liver disease; NAFLD; Steatosis; CAP; Controlled Attenuation Parameter; FibroScan; Niet-alcoholische leververvetting; Steatose;

Sponsors and support

Primary sponsor: Prof. J. Stoker
Professor of Radiology
Department of Radiology
Academic Medical Center Amsterdam
Source(s) of monetary or material Support: Prof. J. Stoker
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Department of Radiology
Academic Medical Center Amsterdam

Intervention

Outcome measures

Primary outcome

Effect of a standardized amount of fat intake on CAP-values.

Secondary outcome

Serum Triglyceride levels (at least first 3 subjects).

Study description

Background summary

CAPtivating is a study in which the CAP-measurement of liver fat content is compared to two reference standards for liver fat: histology and MR-based liver fat fractions. In this part of the study, 8 healthy subjects with no fatty livers are measured with CAP before and hourly up to six hours after ingestion of cream as a fatty meal challenge to investigate the influence of meals on the CAP-measurement.

All subjects are recruited in the Netherlands (in the AMC).

Study objective

Hepatic steatosis is becoming a large health burden in both Western and non-Western societies. There is a need for specific diagnostic tools that can distinguish between patients with significant steatosis and those without whilst simultaneously quantifying the amount of steatosis. Quantification will help clinicians to guide therapy. Several tools exist, but all suffer from shortcomings. A new tool for quantifying steatosis is the Controlled Attenuation Parameter (CAP), available on the FibroScan® (a device used to determine the presence of liver fibrosis). This tool gives a continuous outcome measure and has thus far been evaluated mainly against semi-quantitative scoring of liver biopsies and not against other continuous outcome measures such as 1H-MR Spectroscopy or MRI based liver fat-maps. Neither has the effect of meals on the CAP-value been investigated. In this study, we hypothesize that the ingestion of a standardized amount of fat (cream) does not influence the CAP-value as measured with the FibroScan®.

Study design

1. CAP-values with FibroScan device (measured at screening, baseline and hourly up to six hours after ingestion of cream as a fat challenge);

2. Serum Triglyceride levels: Blood drawn out baseline and hourly up to six hours after ingestion of cream as a fat challenge.

Intervention

In this cohort, 8 fasting subjects will be given cream (35 grams fat / 100 ml) to drink as a fat challenge. Subjects will be given 30 grams of fat per square meter of body surface area, calculated with the DuBois-DeBois method. Before administration and hourly up to six hours after administration CAP-measurements will be performed to ascertain whether a fatty meal induces changes in the CAP-value.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male or Female Sex;

2. 18 years or older;

3. FibroScan-measurement possible with M-probe;

4. No history of liver disease.

Exclusion criteria

1. Alcohol consumption of >3 units per day for male and >2 units per day for females;

2. Focal liver lesion(s) in the right liver lobe (proven with histology results or imaging);

3. Start of or change in treatment of liver disease less than 4 weeks before visit 1;

4. Fibroscan®/CAP examination not possible with M-probe;

5. Dairy intolerance;

6. CAP-value of 300 dB m-1 or more at screening.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2013
Enrollment:	8
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-02-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41661
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3669
NTR-old	NTR3839
CCMO	NL41865.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41661

Study results

Summary results
N/A