Validation of liver fat percentage measurements using different imaging techniques

Published: 13-04-2016
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Objective: to determine the comparability of the liver quantification using the Dixon MRI technique on the Siemens scanner with the MRS technique on the Phillips scanner.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON43628

Source
ToetsingOnline

Brief title
Fatty liver Imaging

Condition

- Other condition

Synonym
liver fat percentage; Non-alcoholic fatty liver disease (NAFLD)

Health condition

geen; het betreft een vergelijking van 2 beeldvomende technieken in gezonde personen

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,EFRO;Stichting de Weijerhorst

Intervention

Keyword: Dixon Magnetic Resonance Imaging (MRS), Fatty Liver, Imaging, Magnetic Resonance Spectroscopy (MRS)

Outcome measures

Primary outcome

Main study parameters/endpoints: Quantification of the liver fat content using

firstly the Dixon MRI technique on the Siemens scanner and secondly the MRS

technique on the Phillips scanner.

Secondary outcome

not applicable

Study description

Background summary

Rationale: Proton magnetic resonance spectrometry (1H-MRS) is considered the gold standard for quantification of liver fat content. However, MRS is relatively expensive and time-consuming. Therefore, MRI (specifically: mDixon MRI) is often used as an alternative method. Within the facilities of the Maastricht University, there are currently 3 options that are regularly used to measure liver fat percentage. These are the Philips MRI and MRS and the Siemens MRI technique. Validation of the Dixon MRI technique with the gold standard technique (MRS) has already been performed for the Philips scanner. However, validation data are not yet available for the Siemens MRI scanner that is present on the UM premises

Study objective

Objective: to determine the comparability of the liver quantification using the Dixon MRI technique on the Siemens scanner with the MRS technique on the

Phillips scanner.

Study design

Study design: Observational study, validation study

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: MRI &MRS do not have any known side effects. Any beneficial or adverse effects will be null since the results of the additional MRS scan will not differ from the scan that is already done within the context of the Maastricht study. The additional scan will take additional time. The estimated time for the MRS procedure * including transfer between building is less than 2 hrs

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

Universiteitssingel 50
Maastricht 6229 ER
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

Universiteitssingel 50
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Participants must:
(1) Undergo abdominal MRI within the context of the ongoing Maastricht study
(2) Fall within the waist categories <75 cm / 75-85 cm / 85-95 cm/ 95-105 cm/105-115 cm/>115 cm

Exclusion criteria

age<40 yrs and age>75 yrs

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-07-2016
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	13-04-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

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	NL53972.068.15