3.0 Tesla MR Spectroscopy for the assessment of hepatic steatosis in severely obese patients before and after weight reduction

Published: 25-10-2007
Last updated: 09-05-2024

- Is there a correlation between liver fat content and inflammation in patients with or without STNFR-2 polymorphisms (-1031C, -863A)?- What is the correlation between weight reduction and decrease of hepatic steatosis?- What is the correlation…

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON30836

Source
ToetsingOnline

Brief title
MR Spectroscopy for the assessment of hepatic steatosis in obese patients

Condition

- Hepatic and hepatobiliary disorders

Synonym
fatty liver, non-alcoholic fatty liver disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: hepatic steatosis, MR Spectroscopy, obesity

Outcome measures

Primary outcome

Assessment of hepatic steatosis with 3.0 Tesla MR Spectroscopy in severely obese patients before and after weight reduction established by bariatric surgery and its correlation with clinical parameters and blood tests

Secondary outcome

Assessment of hepatic steatosis with 3.0 Tesla MR Spectroscopy in severely obese patients before and after weight reduction established by bariatric surgery and its correlation with clinical parameters and blood tests

Study description

Background summary

Hepatic steatosis is a benign condition characterized by an accumulation of lipids in the liver. It is related to a range of etiological features such as obesity, diabetes and dyslipidemia (the metabolic syndrome). Steatosis can progress into a more serious variant, NASH (Non Alcoholic Steato Hepatitis). This condition is associated with an inflammatory component, and in approximately 20 percent of the patients it will ultimately result in liver cirrhosis. Non-alcoholic fatty liver disease (NAFLD) is the term for the spectrum of steatosis, NASH and cirrhosis, and is now recognized as the most common chronic liver disease in the western world, affecting approximately 30 % of the western population. These numbers are thought to increase even further due to the obesity epidemic. Liver biopsy and histological examination has been the reference standard for assessing hepatic steatosis but sampling errors are considerable because of inhomogeneous distribution of fat in the liver. However, imaging techniques (abdominal ultrasound and computed tomography) are also prone to error and lack sensitivity and specificity. Proton Magnetic Resonance Spectroscopy (1H-MRS) is a safe, non-invasive and reproducible

diagnostic tool that allows the semi-quantification of various components of fat in the liver

Study objective

- Is there a correlation between liver fat content and inflammation in patients with or without STNFR-2
polymorphisms (-1031C, -863A)?
- What is the correlation between weight reduction and decrease of hepatic steatosis?
- What is the correlation between a reduction of steatosis and improvement of insulin sensitivity?
- Does a decrease in hepatic steatosis relate to a decrease of inflammation in individuals with positive
inflammation parameters?

Study design

In this prospective pilot study consenting consecutive patients with severe overweight will undergo bariatric surgery. After informed consent we intend to perform MR Spectroscopy of the liver before surgery and 4 months after surgery, as well as assessment of clinical parameters and blood tests. 1H*MRS will be performed by the department of Radiology, assessment of clinical parameters and blood tests will be performed by the department of Hepatology/ AMC liver center. Because the sensitivity and specificity of 3.0 Tesla 1H*MRS for the measurement of hepatic steatosis is unknown, we were not able to calculate by power analysis the number of subject required for the study. Therefore we intend to include 30 patients. A lower number of individuals can be expected to lead to insufficient numbers to study the study objectives

Study burden and risks

The patients in this study will undergo bariatric surgery (standard treatment), two 1H-MRS scans and two clinical assessments and blood sampling. 1H-MRS is a non-invasive, non-ionizing 45 minute examination in the MRI scanner, which requires two extra visits to the hospital. The patient has to lie still on his back in a MRI scanner for about 45 minutes. There is not a direct advantage for the patient, except for extra insight in their disease. Patients are not delayed in treatment for their disease. There will be little extra physical and psychological discomfort associated with participation.

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

Patients over 18 years of age
Patients who will undergo bariatric surgery for weight reduction at the Rijnstate hospital in Arnhem

Exclusion criteria

Patients with extreme obesity (maximum weight limit MRI scanner 150kg, diameter 60 cm)
Patients under 18 years of age
Patients who are pregnant
Patients who are claustrophobic
Patients who have magnetic or radiofrequency sensitive implants

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

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	NL19636.018.07