Study on dietary fat retention in liver using MRI

No registrations found.

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

Summary

ID

NL-OMON28348

Source
Nationaal Trial Register

Brief title
Tracking 13C fatty acids in vivo

Health condition

Fatty liver/NAFLD, type 2 diabetes (T2DM).

Sponsors and support

Primary sponsor: Maastricht University Medical Center
Source(s) of monetary or material Support: Top Institute Food and Nutrition (TIFN)

Intervention

Outcome measures

Primary outcome

The main study parameters per study-group are:

Studie 1 (lean subjects)

- Determination of the lowest dose that allows for sufficient signal to noise ratio and to

determine time of maximal 13C accumulation in liver. Time point of maximal increase.

Studie 2 (obese subjects)

- Minimal dose for significant postprandial increase of enrichment in liver.

- Time point of maximal increase.

- Difference in dose compared to lean subjects.

Secondary outcome

• Total- and 13C-enriched blood plasma levels of FFA, triglycerides, glucose.

Study description

Study objective

Using non-invasive imaging techniques, fat accumulation and metabolism can be studied in ectopic fat stores. Particularly interesting in the field of food and nutrition is the application of 13C magnetic resonance spectroscopy (MRS) to follow the time-course of retention of dietary fat in human tissues in ‘real-time’. The objective is to develop and validate an in vivo magnetic resonance method to track 13C-labeled fatty acids to the liver in healthy subjects.

Study design

0h, 1.5h, 3h, 4.5h and 6h after the meal

Intervention

High fat meal with 13C labeled fatty acids

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria:

Lean subjects (study 1):

- Age 18-65 years

- Normal BMI 18-25 kg/m2

- Stable dietary habits

- Generally healthy, no medication use

Obese subjects (study 2):

- Age 18-65 years,

- Obese, BMI 30-35 kg/m2

- Stable dietary habits (no weight-reducing diet last year)

- Generally healthy, no medication use

Exclusion criteria

Persons that have any of the following will be excluded from the study:

- Any medical condition requiring treatment and/or medication use

- Alcohol consumption of more than 20 g per day (± 2 units) or other drug abuse

- Unstable body weight (weight gain or loss > 3 kg in the past three months)

- Contraindications for MRI scan:

• Aneurysm clips

• Implanted neural stimulator

• Implanted cardiac pacemaker of defibrillator

• Cochlear implant

• Iron- containing corpora aliena in the eye or brain

• Artificial (heart) valves which is contraindicated for MRS

• Claustrophobia

- Subjects, who do not want to be informed about unexpected medical findings, or do not wish that their treating physician is informed, cannot participate in the study. Possible unexpected findings could include: dark or highlighted spots in the liver or contrast differences between different muscle groups. In case one of those unexpected findings are recognised by the performing researcher, a radiologist will be contacted first for advice. On his/her advice further investigations will be performed and/or the physician will be contacted.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2012
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-10-2015
Application type:	First submission

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
NTR-new	NL5275
NTR-old	NTR5557
Other	METC 12-2-034 : ABR38120

Study results