Postprandial Intrahepatic Lipid (IHL) and Intramyocellular Lipid (IMCL) levels measured with Proton Magnetic Resonance Spectroscopy (1H-MRS)

Published: 18-07-2012
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The major research objective is to assess the potential of 1H-MRS to follow IHL and IMCL dynamics after a single meal.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON39035

Source
ToetsingOnline

Brief title
Postprandial IHL and IMCL with 1H-MRS

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
fat accumulation in liver and muscle, Insulin resistance

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 1H-MRS, IHL, IMCL, Postprandial

Outcome measures

Primary outcome

The change of IHL and IMCL concentrations in the late postprandial phase,

compared to baseline measurement after an overnight fast.

Secondary outcome

We also aim to investigate whether the addition of protein to a high fat

breakfast (HFP) results in a reduced postprandial accumulation of lipids when

compared to a high fat breakfast (HF) alone.

Study description

Background summary

Fat accumulation in non-adipose tissue, such as liver and muscle, is associated with reduced insulin sensitivity and cardiovascular disease. Little is known about the dietary determinants and the time course of ectopic fat accumulation and therefore the general aim of this project is to develop and validate methodology to follow postprandial hepatic and muscular lipid retention. Proton Magnetic Resonance Spectroscopy (1H-MRS) is a well-established tool for noninvasive quantification of intrahepatic lipids (IHL) and intramyocellular lipids (IMCL). Previous studies have suggested a relatively rapid regulation of IHL and IMCL levels, indicated by changes in these total lipid pools after high fat diets of 3 or 4 days. Although IHL and IMCL levels seem to change rapidly, data on IHL and IMCL levels after a single meal are lacking.

Study objective

The major research objective is to assess the potential of 1H-MRS to follow IHL and IMCL dynamics after a single meal.

Study design

In a randomized crossover study, IHL and IMCL concentrations will be determined

after a high-energy HF breakfast and after a high-energy HFP breakfast, using 1H-MRS at various time points in a postprandial period of 6 hours.

Intervention

Subjects will report to the university at 7.00 h, after a 9 hours (overnight) fasting period. They will undergo a 1H-MRS scan to determine baseline IHL and IMCL levels. Subsequently the subjects will consume either a high-energy HF breakfast or a high-energy HFP breakfast, and during the late postprandial phase (3h and 5h) IHCL and IMCL levels will be measured again. In addition to the MRS measurements, seven blood samples will be collected at different time points.

Study burden and risks

Subjects will have to come to the university three times. The first time the subjects will be screened to access eligibility, which will include filling in of a medical history questionnaire and a physical activity questionnaire and measurement of height and body weight. Body composition will also be accurately determined by hydrostatic weighing.

During the second and third visit the MRS measurements will be performed. Subjects are asked to report to the university at 7.00 AM. A first MRS scan of liver and muscle is performed prior to the breakfast. At 8.15 AM the subject will have either a high-energy HF breakfast or a high-energy HFP breakfast. The breakfast will consist of sausage rolls. The added proteins will be consumed as a protein powder dissolved in water. Three and five hours after the breakfast, again IHCL and IMCL levels will de determined. Blood samples will also be taken, at different timepoints in between the MR measurements. This means a total of 3 MRS scans and 7 blood samples.

The experimental procedures are without significant risks. MRS is a safe procedure (no ionizing radiation), with no known health risk as long as none of the exclusion criteria is met. There is a chance that MRI reveals an unexpected medical condition, of which the subject will be informed. His physician will also be informed.

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

- Age 18-65 years
- Healthy
- Stable dietary habits
- No use of medication
- Lean subjects: BMI 18-25 kg/m2
- Obese subjects: BMI 30-35 kg/m2

Exclusion criteria

- Any medical condition requiring treatment and/or medication use
- Alcohol consumption of more than 20 g per day (± 2 units)
- Smoking
- Unstable body weight (weight gain or loss > 3 kg in the past three months)
- Participation in another biomedical study within 1 month prior to the screening visit
- Contraindications for MRI scan (cochlear implant, pacemaker, claustrophobia)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-09-2012
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	18-07-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	10-04-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL40593.068.12