The effect of a low compared to a high glycemic index/saturated fatty acid diet on hepatic fat

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Primary Objective: To investigate whether a two-week low compared to high GI/SFA diet reduces liver fat content. Exploratory Objectives: To investigate whether a two-week low compared to high GI/SFA diet:* reduces DNL* lowers the 24-hour glycemic…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON54906

Source
ToetsingOnline

Brief title
GI/SFA diet and hepatic fat

Condition

- Hepatic and hepatobiliary disorders
- Lipid metabolism disorders

Synonym
fatty liver, Non-alcoholic fatty liver (NAFL)

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: TKI,Unilever

Intervention

Keyword: diet, glycemic index, hepatic fat, saturated fatty acids

Outcome measures

Primary outcome

Liver fat content (measured by 1H-MRS)

Secondary outcome

Explorative study parameters:

- de novo lipogenesis (DNL) measured as relative contribution of newly

synthesized palmitate in the VLDL-TG pool expressed as %DNL.

- hepatic fat oxidation measured as plasma beta-hydroxybutyrate (BHB)

- hepatic glycogen content (13C-MRS)

- substrate oxidation

- plasma metabolites related to energy metabolism

- liver fat composition (1 H-MRS)

- 24h glycemic response

Study description

Background summary

The liver plays an important role in fat metabolism. Disturbances in liver fat metabolism can lead to accumulation of fat in the liver. This hepatic fat storage is also called non-alcoholic fatty liver, when excessive alcohol use is not the cause. A non-alcoholic fatty liver is associated with negative effects on metabolic health, such as cardiovascular disease and type II diabetes.

Nutrition can influence liver fat storage. However, not only the amount fats and carbohydrates, but also their quality have been shown to influence liver

fat. The few studies performed show that diets high in saturated fatty acids (SFA) and diets with a high glycemic index (GI) increase liver fat content. However, the diets in these studies are unrealistic compared to current dietary guidelines. Here we want to combine low GI/SFA on the one hand and high GI/SFA on the other hand to reflect realistically a healthy and an unhealthy diet as they are actually consumed by the Dutch population. We exptect that a low GI/SFA diet results in lower liver fat content compared to a high GI/SFA diet.

Study objective

Primary Objective:
To investigate whether a two-week low compared to high GI/SFA diet reduces liver fat content.

Exploratory Objectives:
To investigate whether a two-week low compared to high GI/SFA diet:
* reduces DNL
* lowers the 24-hour glycemic response
* lowers hepatic glycogen content
* increases plasma BHB levels
* changes hepatic lipid composition
* changes other plasma metabolites related to energy expenditure
* changes energy expenditure and substrate oxidation

Study design

This is a randomized cross-over study comparing the effects of a 2-week high GI/SFA compared to a 2-week low GI/SFA diet. The diets will be interspersed by a washout period of minimal 4 weeks.

Intervention

Participants will adhere to two diets differing in GI and SFA content for 2 weeks each: a two-week low GI/low SFA diet and a two-week high GI/high SFA diet. Diets will be comparable in macronutrient content, but will differ in fatty acid composition and GI. Examples of products included in the low GI/low SFA diet include: semi-skimmed milk, rye bread, bulgur, brown rice, tuna, chicken, turkey, nuts, fresh vegetables. Examples of products included in the low GI/low SFA diet include: Potatoes, meatballs, beef, chocolate pudding, white bread, mature 48+ cheese, orange juice.
Energy percentages (en%) of carbohydrates, fats and protein will be matched and will be around 55-60, 25-30, 10-15, respectively. The intended fatty acid composition of the low GI/SFA diet is 6, 10 and 12 en% saturated, mono-unsaturated and poly-unsaturated respectively, while for the high GI/SFA en% will be 14, 10 and 4, respectively. The intended GI of the low GI/SFA diet

will be 35-40% and the intended GI of the high GI/SFA diet 60-65%.

Study burden and risks

Results of this study will provide insight in the effect of a low GI/SFA compared to a high GI/SFA diet on liver fat and will provide information on the potential mechanisms underlying these effects on liver fat. The risks of the performed measurements and the physical discomfort are low; risks related to the MRS measurements and meal-test are low because of clear exclusion criteria aimed at reducing risks and the well-experienced researchers performing these tests and isotopically-labelled water ingestion is entirely safe and non-toxic with body water enrichment up to 20 mol%.

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

- Signed informed consent
- Caucasian (people will be excluded when having a *50% racial African/Asian background)
- Male or postmenopausal female
- Aged 45-75 years at start of the study
- Body mass index (BMI) 27 * 38 kg/m2
- Stable dietary habits (no weight loss or gain >3kg in the past 3 months)
- Sedentary lifestyle (not more than 2 hours of sports per week)
- TG between 1.0 and 4.0 mmol/L

Exclusion criteria

- Type 2 diabetes
- Any acute condition, exacerbation of chronic condition, or medical history that would in the investigator*s or dependant physician's opinion interfere with the study
- Contra-indication for MRI
- Alcohol consumption of >2 servings per day
- Smoking
- Vegetarian, vegan, food intolerant to common foods (e.g. gluten intolerant, lactose intolerant)
- Use of medication known to interfere with the safety of study procedures

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):	15-08-2019
Enrollment:	29
Type:	Actual

Ethics review

Approved WMO Date:	03-07-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-11-2020
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	NL69685.068.19