

Effects of low-fat vs high-fat diet on lipid accumulation in liver and skeletal muscle in overweight men.

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A high fat-diet can influence IMCL and IHL in rodents and in humans, the time-course of peripheral lipid accumulation in liver and skeletal muscle while switching from a low-fat to a high-fat diet is unknown.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19938

Bron

Nationaal Trial Register

Verkorte titel

High-fat vs Low-fat diet

Aandoening

Type 2 diabetes (T2DM), Insulin resistance, Non-Alcoholic Fatty Liver Disease (NAFLD)

Type 2 diabetes, insuline resistentie en leververvetting

Ondersteuning

Primaire sponsor: School for Nutrition, Toxicology and Metabolism of Maastricht University Medical centre + (MUMC+)

Overige ondersteuning: TI Food & Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main study parameter is the difference in lipid accumulation and insulin sensitivity after a switch from a low-fat diet to a high-fat diet compared to the control group, which stays on a low-fat diet.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

A high fat-diet can influence IMCL and IHL in rodents and in humans, the time-course of peripheral lipid accumulation in liver and skeletal muscle while switching from a low-fat to a high-fat diet is unknown.

Onderzoeksopzet

T=1, T=21 and T=42 (days).

And additional liver lipid accumulation measurement in HF-group on t=28.

Onderzoeksproduct en/of interventie

Both groups, the control group and the experimental group, will start with 3 weeks on a low-fat diet which will deliver 15 Energy% of energy as protein, 65 En% as CHO and 20 En% as fat. After these 3weeks the experimental group will switch to a high-fat diet (15 En% protein, 30 En% CHO and 55% En% fat). whereas the control group stays on the low-fat diet.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male sex;
2. Age 40-65 years;
3. BMI 25-35 kg/m²;
4. Sedentary;
5. Stable dietary habits;
6. Healthy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Current use of medication that is known to interfere with the results of the study;
2. Consuming more than 20 g of alcohol per day ($\pm$ 2 units);

3. Serum- γ -glutamyltranspeptidase level > 70 IU/L;
4. A history of cardiovascular disease like congestive heart failure or acute myocardial infarction;
5. Plasma triacylglycerol > 4.5 mmol/L;
6. Familial hypercholesterolemia;
7. A history of liver disease;
8. Unstable body weight (weight gain or loss > 3 kg in the past three months);
9. Abuse of drugs;
10. Participation in another biomedical study within 1 month prior to the screening visit;
11. Impossible or difficult venipuncture during screening;
12. A fasting glucose above 7.0 mmol/L (13);
13. A contraindication to MRI scanning. These contraindications include patients with the following devices:
 - a. Central nervous system aneurysm clips;
 - b. Implanted neural stimulator;
 - c. Implanted cardiac pacemaker or defibrillator;
 - d. Cochlear implant;
 - e. Ocular foreign body (e.g. metal shavings);
 - f. Insulin pump;
 - g. Metal shrapnel or bullet;
 - h. Or metal containing corpora aliena in the eye of brains.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2007
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	10-12-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2019

Register

NTR-old

Ander register

ISRCTN

ID

NTR2136

MEC : 07-3-028

ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A