

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

No registrations found.

| | |
|------------------------------|---------------------|
| Ethical review | Positive opinion |
| Status | Recruitment stopped |
| Health condition type | - |
| Study type | Interventional |

Summary

ID

NL-OMON19938

Source

NTR

Brief title

High-fat vs Low-fat diet

Health condition

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

Type 2 diabetes, insuline resistentie en leververvetting

Sponsors and support

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

Source(s) of monetary or material Support: TI Food & Nutrition

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

As secondary endpoints differences the time-course of lipid accumulation and the relationship between the tissue parameter lipid accumulation and the functional outcome parameter insulin resistance are considered.

Study description

Background summary

N/A

Study objective

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.

Study design

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

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

Intervention

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.

Contacts

Public

Postbus 616

Department of Human Biology

Maastricht University Medical Center

Patrick Schrauwen
Department of Human Biology
Maastricht University Medical Center
Maastricht 6200 MD
The Netherlands
+31(0)43-388 15 02

Scientific

Postbus 616
Department of Human Biology
Maastricht University Medical Center
Patrick Schrauwen
Department of Human Biology
Maastricht University Medical Center
Maastricht 6200 MD
The Netherlands
+31(0)43-388 15 02

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

Study type: Interventional

Intervention model: Parallel

| | |
|-------------|-----------------------------|
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

Recruitment

| | |
|---------------------------|---------------------|
| NL | |
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-07-2007 |
| Enrollment: | 20 |
| Type: | Actual |

Ethics review

| | |
|-------------------|------------------|
| Positive opinion | |
| Date: | 10-12-2009 |
| 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 | NL2019 |
| NTR-old | NTR2136 |
| Other | MEC : 07-3-028 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

Study results

Summary results

N/A