# The effect of body fat distribution on the physiological response to a dietary fat intervention.

Published: 12-06-2007
Last updated: 08-05-2024

The primary objective is to examine the effect of body fat distribution on the physiological response to a dietary fat intervention. Physiological response will be evaluated as fatty acid kinetics (plasma and subcutaneous fat appearance), targeted...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON31240

**Source**
ToetsingOnline

**Brief title**
Body fat distribution and fat metabolism

### Condition

- Other condition

**Synonym**
Obesity, overweight

**Health condition**

Overgewicht/obesitas

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** TNO
**Source(s) of monetary or material Support:** Ministerie van VWS

## Intervention

**Keyword:** body fat distribution, chain length, fat metabolism, fatty acids, obesity, stable isotopes

## Outcome measures

### Primary outcome

Main study parameters/endpoints: On the last day (day 21 and day 63) of each

treatment period subjects will come to the metabolic ward of TNO for evaluation

of the effect of the dietary intervention on fat metabolism and fat tissue.

This will be examined with stable isotope techniques and fat biopsies of

subcutaneous fat.

The primary objective of the study is to investigate the effect of chain length

of the fatty acid consumed on kinetics of fat metabolism and fat disposition

(centrally or subcutaneously).

### Secondary outcome

2. leucine tracers in blood as a measure for lipoprotein synthesis and

degeneration ;

3. changes in fat tissue characteristue due to the intervention;

4. satiety hormones and scores.

# Study description

## Background summary

Rationale: The increased prevalence of obesity and the related risk for metabolic diseases have resulted in increased interest in prevention of obesity through life-style interventions. The site of fat storage (visceral or subcutaneous) is considered to be relevant in terms of risk for metabolic disorders. The type of fat consumed may determine storage in either fat storage site and hence be related to metabolic disorders. Long-chain fatty acids have been suggested to be preferentially targeted to subcutaneous fat, whereas medium chain fatty acids may preferably be targeted to the visceral fat depot.

## Study objective

The primary objective is to examine the effect of body fat distribution on the physiological response to a dietary fat intervention. Physiological response will be evaluated as fatty acid kinetics (plasma and subcutaneous fat appearance), targeted protein production (apoB and adiponectin) and satiety.

## Study design

The study is designed as a randomized, double-blind, cross-over trial.

## Intervention

Two treatments will be supplied for three weeks, with a wash-out period of at least 3 weeks in-between.

Two treatments will be given: three weeks with a fat supplement containing long chain fatty acids and three weeks with a fat supplement containing medium chain fatty acids. The margarines will replace the normally consumed margarine. Consumption will take place with each bread meal and dinner (20 grams of spread with each meal). This is equal to 48 grams of fat (margarines contain 80% of fat).

## Study burden and risks

At baseline subjects will have a total body scan in the MRI to characterize body fat. In the study subjects will come twice to TNO for an internal day at which stable isotopes will be administered (intravenously and orally). On each test day 19 blood samples will be obtained (per test day not more than 240 mL blood will be collected). On each test day three fat biopsies will be obtained (at t=0, 3 and 6 hours). Consumption of the test spread is not considered as a burden, because the fatty acids supplied are normally consumed fatty acids, in amounts within the normal range.
The groups of overweight and obese subjects is selected for this study, because of their visceral and subcutaneous fat stores which might influence the effect

of the fat supplement intervention on fat kinetics differently.

## Contacts

**Public**
TNO

Postbus 360
3700 AJ
Nederland
**Scientific**
TNO

Postbus 360
3700 AJ
Nederland

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

Inclusion criteria:
1. Healthy as assessed by the health and lifestyle questionnaire, physical examination and results of the pre-study laboratory tests;
2. Males aged between 30 - 60 years at Day 01 of the study;
3. Overweight/obese subjects, Body Mass Index (BMI) between 27-35 kg/m2 ;
4. Range in waist-hip ratio as high as possible (preferably below 0.90 or above 0.95);
5. Regular Dutch eating habits as assessed by P7261 F02 and used to consume margarine;
6. Non restrained eater, defined as a score of <3.25 in obese men on the Dutch Restrained Eating Questionnaire;

7. Appropriate veins for blood sampling / cannula insertion according to TNO employees;
8. Voluntary participation;
9. Having given written informed consent;
10. Willing to comply with the study procedures (consumption of the fat supplements for three weeks and the last days testing at TNO);
11. Agree to be informed about chance findings of pathology found with the MRI;
12. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years;
13. Willing to accept the disclosure of the financial benefit of participation in the study to the authorities concerned.

### Exclusion criteria

Exclusion criteria:
1. Participation in any clinical trial including blood sampling and/or administration of substances up to 90 days before Day 01 of this study;
2. Participation in any non-invasive clinical trial up to 30 days before Day 01 of this study, including no blood sampling and/or oral, intravenous, inhalatory administration of substances;
3. Having a history of medical or surgical events that may significantly affect the study outcome, including any psychiatric history, and metabolic or endocrine disease, or any gastro-intestinal disorder;
4. Use of medication that may influence appetite, and/or sensory functioning within 14 days before day 01, except paracetamol;
5. Smoking;
6. Alcohol consumption (> 28 units/week);
7. Contra-indication to MRI scanning (claustrophobia; pacemakers and defibrillators; nerve stimulators; intracranial clips; intraorbital or intraocular metallic fragments; cochlear implants; ferromagnetic implants; presence of any other metal object e.g. in the mouth);
8. Reported unexplained weight loss or gain of > 2 kg in the month prior to the pre-study screening;
9. Reported slimming or medically prescribed diet;
10. Reported vegan, vegetarian or macrobiotic;
11. Recent blood donation (<1 month prior to the start of the study);
12. Not willing to give up blood donation during the study;
13. Personnel of TNO Quality of Life, their partner and their first and second degree relatives;
14. Not having a general practitioner;
15. Not willing to accept information-transfer concerning participation in the study, or information regarding his health, like laboratory results, findings at anamnesis or physical examination and eventual adverse events to and from his general practitioner.

## Study design

### Design

| | |
|---|---|
| Study phase: | 2 |
| Study type: | Interventional |
| Intervention model: | Crossover |
| Masking: | Double blinded (masking used) |
| Control: | Uncontrolled |
| Primary purpose: | Other |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 18-06-2007 |
| Enrollment: | 12 |
| Type: | Anticipated |

## Ethics review

Approved WMO

| | |
|---|---|
| Application type: | First submission |
| Review commission: | METC Brabant (Tilburg) |

## 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 | NL17251.028.07 |