# The effects of macronutrients on postprandial vascular function in overweight and slightly obese men

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Lipid metabolism disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON47116

**Source**
ToetsingOnline

**Brief title**
Macronutrients and postprandial vascular function

### Condition

- Lipid metabolism disorders

**Synonym**
Insulin Resistance Syndrome, Metabolic Syndrome, Syndrome X

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universiteit Maastricht
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Macronutrients, Vascular function

## Outcome measures

### Primary outcome

Measurements will be performed before and two hours after consumption of the milkshakes. The primary endpoint is the difference in postprandial change in FMD between the HF-LC-LP, LF-HC-LP and LF-LC-HP meal.

### Secondary outcome

Secondary outcomes are the postprandial effects of a HF-LC-LP, LF-HC-LP and LF-LC-HP meal on other markers reflecting vascular function (PWA, PWV and retinal microvascular caliber), plasma markers for low-grade systemic inflammation and endothelial dysfunction, blood pressure, and serum lipid and plasma glucose metabolism.

# Study description

### Background summary

Vascular function may decrease following the intake of a mixed meal in some but not all studies. Differences in the relative amounts of dietary fat, carbohydrates and protein present in the mixed-meal challenges may have contributed to these apparently inconsistent results. Well-designed trials comparing under rigorously standardized conditions effects of macronutrients on postprandial vascular function are missing.

### Study objective

The primary objective of the proposed study is to evaluate the effect of the three macronutrients on postprandial vascular function, assessed by brachial artery flow-mediated vasodilation (FMD), in overweight and slightly obese male volunteers. Secondary objectives are to examine postprandial effects on other markers reflecting vascular function, plasma markers for low-grade systemic

inflammation and endothelial dysfunction, blood pressure, and serum lipid and plasma glucose metabolism.

### Study design

The proposed study will have a randomized, double-blind cross-over design. The total study duration will be at least 15 days, including three test days, each separated by a washout period of at least 1 week.

### Intervention

During each of the three experimental days, the volunteers will participate in a postprandial test. For this, they receive in random order a high-fat (HF-LC-LP) milkshake, high-carbohydrate (LF-HC-LP) milkshake or high-protein (LF-LC-HP) milkshake. The total follow-up during each of the postprandial tests is 4 hours.

### Study burden and risks

Subjects will be screened to determine eligibility during one visit of 15 minutes. During these screening visits, anthropometric measurements will be performed and blood pressure will be determined. In addition, a venous blood sample (9.0 mL) will be drawn. During the study, there will be three test days in which subjects receive in random order a HF-LC-LP milkshake, a LF-HC-LP milkshake or a LF-LC-HP milkshake. There are no directs benefits for the participants. Investigational products are safe and all ingredients to prepare the milkshakes are commercially available and approved for human consumption. There are no side effects related to the consumption of the milkshakes. On the experimental days a postprandial test will take place and blood will be sampled (3 x 105.0 mL with an interval of at least one week inter-between). During the 4-hour postprandial period, participants are allowed to drink one glass of water and are free to walk-around. Some study subjects may report pain during venipuncture. Insertion of the cannula can cause some discomfort and possible a hematoma or bruise. Some men may also report pain during the insertion of the cannula. Vascular measurements will be performed before and two hours after meal intake. These measurements are routine and not expected to lead to physical side effects. Study participants that not fully adhere to the study protocol will be excluded from the statistical analyses because a per protocol analysis will be performed. Time investment is approximately 15 hours, excluding travel time.

## Contacts

### Public

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

- Aged between 18-70 years
- Men
- BMI between 25-35 kg/m2 (overweight and slightly obese)
- Fasting plasma glucose < 7.0 mmol/L
- Fasting serum total cholesterol < 8.0 mmol/L
- Fasting serum triacylglycerol < 2.2 mmol/L
- Systolic blood pressure < 160 mmHg and diastolic blood pressure < 100 mmHg
- No current smoker
- No diabetic patients
- No familial hypercholesterolemia
- No abuse of drugs
- No more than 3 alcoholic consumptions per day
- Stable body weight (weight gain or loss < 3 kg in the past three months)
- No use of medication known to treat blood pressure, lipid or glucose metabolism
- No use of an investigational product within another biomedical intervention trial within the previous 1-month

- No severe medical conditions that might interfere with the study, such as epilepsy, asthma, kidney failure or renal insufficiency, chronic obstructive pulmonary disease, inflammatory bowel diseases, auto inflammatory diseases and rheumatoid arthritis
- No active cardiovascular disease like congestive heart failure or cardiovascular event, such as an acute myocardial infarction or cerebrovascular accident
- Willingness to give up being a blood donor from 8 weeks before the start of the study, during the study and for 4 weeks after completion of the study
- No difficult venipuncture as evidenced during the screening visit

### Exclusion criteria

- Women
- Fasting plasma glucose >= 7.0 mmol/L
- Fasting serum total cholesterol >= 8.0 mmol/L
- Fasting serum triacylglycerol >= 2.2 mmol/L
- Systolic blood pressure >= 160 mmHg and/or diastolic blood pressure >= 100 mmHg
- Current smoker, or smoking cessation <12 months
- Diabetic patients
- Familial hypercholesterolemia
- Abuse of drugs
- More than 3 alcoholic consumptions per day
- Unstable body weight (weight gain or loss > 3 kg in the past three months)
- Use medication known to treat blood pressure, lipid or glucose metabolism
- Use of an investigational product within another biomedical intervention trial within the previous 1-month
- Severe medical conditions that might interfere with the study, such as epilepsy, asthma, kidney failure or renal insufficiency, chronic obstructive pulmonary disease, inflammatory bowel diseases, auto inflammatory diseases and rheumatoid arthritis
- Active cardiovascular disease like congestive heart failure or cardiovascular event, such as an acute myocardial infarction or cerebrovascular accident
- Not willing to give up being a blood donor from 8 weeks before the start of the study, during the study or for 4 weeks after completion of the study
- Not or difficult to venipuncture as evidenced during the screening visit

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Crossover |
| Masking: | Double blinded (masking used) |

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| Control: | Uncontrolled |
| Primary purpose: | Prevention |

### Recruitment

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 13-12-2017 |
| Enrollment: | 20 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 18-05-2017 |
| Application type: | First submission |
| 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 | NL60030.068.17 |