# The effects of homogenized and unhomogenized milk on postprandial metabolism in healthy overweight men

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The objective of the study is to compare the effects of homogenized, unhomogenized and skimmed milk with butter on postprandial metabolism in healthy overweight men.

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

## Summary

### ID

NL-OMON36794

**Source**
ToetsingOnline

**Brief title**
Milk and postprandial metabolism

### Condition

- Lipid metabolism disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

**Synonym**
arteriosclerosis, atherosclerosis, hardening of the arteries; Metabolic Syndrome, insulin resistance syndrome, Syndrome X

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universiteit Maastricht
**Source(s) of monetary or material Support:** Nederlandse Zuivel

Organisatie,Nederlandse Zuivel Organisatie (NZO)

## Intervention

**Keyword:** (un)homogenized milk, food matrix, postprandial metabolism, skimmed milk

## Outcome measures

### Primary outcome

The main study parameter are differences in the iAUC of serum triacylglycerol curves.

### Secondary outcome

Secondary endpoints are differences in changes in plasma markers for glucose metabolism, inflammatory markers, and endothelial activity, changes in microcirculation based on retinal imaging and changes in macrocirculation based on PWV measurement.

# Study description

### Background summary

Epidemiological studies have suggested that dairy products may lower the risk to develop cardiovascular disease, even though these products can be high in saturated fatty acids and cholesterol, which raise serum LDL cholesterol concentrations. This apparent discrepancy may be related to beneficial effects of dairy products on postprandial metabolism, another risk marker for cardiovascular disease. As people spend most of the day in the postprandial phase, this is an important finding, especially for overweight and obese subjects who have an increased risk for postprandial metabolic disturbances. Discrepancies, however, exist between studies. This may be related to differences in the type of dairy products used. We now hypothesize that the food matrix of dairy products is an important characteristic of the postprandial response.

### Study objective

The objective of the study is to compare the effects of homogenized,

unhomogenized and skimmed milk with butter on postprandial metabolism in healthy overweight men.

### Study design

Using a crossover design, subjects will receive in random order three different meals with a washout period of at least 7 days. During the study, the postprandial response will be measured.

### Intervention

All subjects will receive in a random order three meals: a meal with homogenized whole milk, a meal with unhomogenized whole milk, and a meal with skimmed milk with butter. The amounts of energy will be similar for all meals.

### Study burden and risks

Before the start of the study subjects will be screened to determine eligibility during one 15 and one 10 min visit. During these visits, body weight and height will be measured and a blood sample (3.5 mL) will be drawn by means of venapunction. During the study, each subject will receive each of the three test meals in random order. For this, subjects will visit the department three times. During these visits, a photo of the retina will be taken and an intravenous cannula will be inserted in an antecubital vein. Before and after meal consumption, 13 blood samples (112 mL) will be drawn for the next 8 hours. In total, 343 mL of blood will be sampled (7 mL during screening and 3x112 mL during the study). At timepoint 0 PWV will be measured, which will be repeated after 2, 4, 6 and 8 hours. The retinal imaging will be repeated after 4 and 8 hours. Total time investment for the subjects will be approximately 25 hours. During this period, subjects will be at the university. On rare occasions, blood sampling might cause bruises or haematoma.

## 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

Healthy men will be included. The inclusion criteria are
- aged between 18 and 70 years
- Quetelet index between 25 - 30 kg/m2
- mean serum triacylglycerol (<=1.7 mmol/L)
- no indication for treatment with cholesterol-lowering drugs according to the Dutch Cholesterol Consensus
- no lactose intolerance
- no current smoker
- no familial hypercholesterolemia
- no abuse of drugs
- less than 21 alcoholic consumptions per week
- stable body weight (weight gain or loss < 3 kg in the past three months)
- no use of medication or a diet known to affect serum lipid or glucose metabolism
- no severe medical conditions that might interfere with the study, such as epilepsy, asthma, chronic obstructive pulmonary disease, inflammatory bowel diseases and rheumatoid arthritis.
- no active cardiovascular disease like congestive heart failure or recent (<6 months) event (acute myocardial infarction, cerebro vascular accident)
- no use of an investigational product within the previous 1 month
- willing to stop the consumption of vitamin supplements, fish oil capsules or products rich in plant stanol or sterol esters 3 weeks before the start of the study
- willing to give up being a blood donor (or having donated blood) from 8 weeks before the start of the study and during the study
- no difficult venipuncture as evidenced during the screening visits

### Exclusion criteria

- women
- aged <18 or >70 years
- Quetelet index below 25 or above 30 kg/m2
- mean serum triacylglycerol (>=1.7 mmol/L)
- indication for treatment with cholesterol-lowering drugs according to the Dutch Cholesterol Consensus
- lactose intolerant
- current smoker
- familial hypercholesterolemia
- abuse of drugs
- more than 21 alcoholic consumptions per week
- unstable body weight (weight gain or loss > 3 kg in the past three months)
- use of medication or a diet known to affect serum lipid or glucose metabolism
- severe medical conditions that might interfere with the study, such as epilepsy, asthma, chronic obstructive pulmonary disease, inflammatory bowel diseases and rheumatoid arthritis.
- active cardiovascular disease like congestive heart failure or recent (<6 months) event (acute myocardial infarction, cerebro vascular accident)
- use of an investigational product within the previous 1 month
- not willing to stop the consumption of vitamin supplements, fish oil capsules or products rich in plant stanol or sterol esters 3 weeks before the start of the study
- not willing to give up being a blood donor (or having donated blood) from 8 weeks before the start of the study and during the study
- not or difficult to venipuncture as evidenced during the screening visits

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Masking: | Single blinded (masking used) |
| Control: | Uncontrolled |
| Primary purpose: | Prevention |

### Recruitment

NL
Recruitment status: Recruitment stopped

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|---|---|
| Start date (anticipated): | 04-04-2011 |
| Enrollment: | 20 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 17-02-2011 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 09-05-2011 |
| 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 |
|---|---|
| ClinicalTrials.gov | NCT01317524 |
| CCMO | NL35010.068.10 |