The effects of different fat structures on postprandial responses in healthy subjects.

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

Summary

ID

NL-OMON48465

Source
ToetsingOnline

Brief title
Postprandial effects of milk fats (POEMI).

Condition

- Other condition

Synonym
immune response, postprandial effects to differences in fat structure

Health condition

metabolisme

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Campina,Friesland Campina

Intervention

Keyword: Genomics, Immune response, Lipid challenge

Outcome measures

Primary outcome

1) whole genome gene expression changes in isolated monocytes from the circulation, 2) postprandial changes in cytokine concentrations in the circulation, and 3) functional responses and sensitivity of the isolated monocytes from the circulation.

Secondary outcome

1) postprandial triglyceride concentration and other cardio-metabolic markers in the circulation, 2) postprandial feelings of hunger and satiety, and 3) changes in cytokine concentrations in the circulation measured in dried blood spots.

Study description

Background summary

Human milk is considered as the ideal food for full-term infants. The composition and function of human milk is unique and has provided the basis for the development of modern artificial milk formulas that mimic its complex biological positive effects on infants and can provide an appropriate substitute for non-breastfed infants. An important component in human milk are the lipids, as they deliver 50% of the total energy to infants. Nowadays, mostly vegetable fat blends are used in infant formula, but the use of bovine milk fat is increasing. In terms of fat structure, bovine milk fat and vegetable fats differ. Bovine milk fat has a higher percentage of palmitic acid

attached to the sn-2 position of the glycerol backbone compared to vegetable fat. Also bovine milk fat contains milk fat globular membranes, as opposed to vegetable fat. Knowledge on how these differences influence underlying mechanistic, immune and metabolic responses is lacking.

Study objective

The primary objective of this study is to determine the effect of three different fat blends on underlying mechanistic and immune responses in the circulation. The secondary objectives of this study are: 1) to examine the effects of the three different fat blends on postprandial triglyceride concentration and other cardio-metabolic markers in the circulation, 2) to investigate the effect of the three different fat blends on postprandial feelings of hunger and satiety, and 3) to investigate how comparable cytokine measurements are in blood samples obtained via catheter cannula compared to cytokine measurements in dried blood spots obtained via a finger prick.

Study design

The POEMI Study is a double*blind randomized cross*over acute intervention study in which each research subject will visit the university on three separate occasions with a wash-out period of at least one week. At each visit the research subject will undergo one of the three dietary lipid challenge tests (a shake) in a randomized order. On each study day, we will insert a catheter cannula in an antecubital vein of the research subject and subsequently wait 30 minutes before continuing with the measurements. After the 30 minute rest, blood will be drawn from the catheter cannula and via a finger prick (baseline measurements, t0). After the baseline measurements, the research subjects will have to consume the shake within a time frame of 10 minutes. Blood is again drawn from the catheter cannula at t= 1, 2, 3, 4, 5, 6, 7, and 8 hours after consumption, with an additional finger prick at t=6. A questionnaire on hunger and satiety feelings will be taken after every blood draw.

Intervention

The dietary lipid challenge tests will be provided in the form of a liquid shake (0.6 L). Each shake will contain 95 gram of fat. The three types of fat that will be tested include: a) 100% vegetable fat blend, b) 100% Anhydrous milk fat (AMF), c) 100% cream (AMF + milk fat globular membranes).

Study burden and risks

Research subjects that participate in this study, will have to invest a total of 31 hours. The total amount of blood collected on each test day will be 158.5 ml, plus once 3 ml during the screening, thus in total 478.5 ml. There are

minor risks for the research subjects during the study. Blood sampling can occasionally cause a local hematoma or bruise and some research subjects may report pain or mild discomfort. The consumption of the high-fat shakes is not expected to be associated with any risk, although in rare cases it could lead to mild gastro-intestinal discomfort. Research subjects will receive ¤300,- after completion of the study. They will also receive a repayment of made traveling expenditures (up to 30 km, one way), a meal the night before each of the three study days, and a meal after each study day.

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

- Apparently healthy man or woman
- Age 40-70y at the time of recruitment

- BMI of 22-27 kg/m2
- Having a Hb value above 8.4 (men) or 7.4 (women) mmol/L (will be checked at the screening visit)
- Having veins suitable for blood sampling via a catheter cannula (judged by study nurse/ medical doctor)
- Having a general practitioner
- Signed informed consent

Exclusion criteria

- Any chronic metabolic, gastrointestinal, inflammatory or chronic disease (such as diabetes, anaemia, hepatitis, cardiovascular disease)
- History of gastro-intestinal surgery or having (serious) gastro-intestinal complaints
- Renal or hepatic malfunctioning (pre-diagnosis or determined based on ALAT, ASAT and creatinine values)
- Use of medication that may influence the study results, such as laxatives, stomach protectors and drugs that can affect intestinal motility.
- Donated or intend to donate blood from 2 months before the study until the end of the study
- Reported slimming, medically prescribed or vegan diet
- Unstable body weight (weight gain or loss >5 kg in the past three months)
- Current smokers
- Alcohol on average: more than 2 consumptions/day or more than 14 consumptions/week
- Pregnant, lactating or wishing to become pregnant in the period of the study (self-reported)
- Use of drugs (soft and/or hard drugs)
- Food allergies for products that we use in the study
- Participation in another clinical trial at the same time, or in the month preceding the start of this study
- Inability to understand study information and/or communicate with staff
- Members of the research team
- Working, or doing an internship or thesis at the division *Human Nutrition and Health*, Wageningen University

Study design

Design

Study type:	Interventional

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-12-2019
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	05-11-2019
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL69492.081.19