The effect of addition of bovine milk fat to infant formula on energy metabolism, postprandial lipid response, chylomicron composition and size, and satiety.

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

Summary

ID

NL-OMON46784

Source
ToetsingOnline

Brief title
MELC study

Condition

- Other condition

Synonym
absorption of lipids, metabolism

Health condition

metabolisme

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: FrieslandCampina Nederland B.V,FrieslandCampina Nederland. B.V

Intervention

Keyword: bovine milk fat, chylomicrons, energy metabolism, postprandial lipid response

Outcome measures

Primary outcome

The main parameter is the diet-induced thermogenesis (DIT). This will be measured for five hours after the consumption of the infant formula products.

Secondary outcome

Secondary study parameters are postprandial lipid profile, respiratory exchange ratio, and triglyceride level, apolipoprotein levels, phospholipid level, fatty acid profile and chylomicron size, which will all be measured in chylomicron-rich fraction of plasma. Furthermore, glucose, insulin and satiety hormone levels will be measured in blood, acetone concentrations in exhaled air and satiety will further be investigated via questionnaires and caloric intake at an ad libitum lunch.

Study description

Background summary

Because of its favourable triglyceride structure for digestion and absorption, bovine milk fat is thought to be a good source of lipids for infant formula. The addition of bovine milk fat also delivers short- and medium-chain fatty acids, which are not or hardly present in vegetable fat mixtures that are

commonly used. It would be interesting to investigate what the effect of those fatty acids is on metabolism. Medium-chain triglycerides are known to affect energy metabolism, since they are easily absorbed and oxidized. It is expected that the short- and medium-chain fatty acids in bovine milk fat have a similar effect. The effect of the triglyceride structure of bovine milk fat on absorption into the blood and the metabolic responses is also not clear. With this study we would like to investigate whether the addition of bovine milk fat to infant formula has a different effect on metabolism then a mixture of vegetable fats only.

Study objective

The primary objective of this study is to investigate if the addition of bovine milk fat to an infant-formula product increases the diet-induced thermogenesis. Secondary objectives are to investigate if the addition of bovine milk fat in an infant formula product influences the: 1) substrate oxidation, 2) postprandial lipid profile, 3) postprandial triglyceride levels in the chylomicron-rich fraction of plasma, 4) chylomicron size and composition, 5) satiety

Study design

This study will be a randomized double-blinded cross-over study which will consist of two study days.

Intervention

The subjects will receive milkshakes made of infant-formula products containing two different fat mixtures; one consisting of 100% vegetables fat and one containing 65% bovine milk fat and 35% vegetable fats.

Study burden and risks

The risks related to this study are minor for the subjects. The participants will be asked to come to the university two times. There will also be a screening visit. On both study days participants will be asked to lie down on a bed with their head placed under a ventilated hood to perform measurements on exhaled air. Blood sampling will take place on several time points, therefore an intravenous cannula will be installed. There is a small risk of bruising and sore muscles after the blood sampling procedures.

Contacts

Public

Wageningen Universiteit

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Caucasian male
* 18-28 years old
* Body mass index (BMI) 20-25 kg/m2.
* Regular consumption of milk (products)
* Haemoglobin (Hb) level > 8.4 mmol/L

Exclusion criteria

* (symptoms of) cow*s milk allergy
* Lactose intolerance
* Metabolic diseases
* (known symptoms of) (auto)immune diseases, like diabetes
* (known symptoms of) gastro-intestinal diseases, like; irritable bowel syndrome
Intestinal malabsorption, diagnosed with celiac disease, Crohn*s disease, colitis ulcerosa, short bowel syndrome or surgical bowel interventions leading to malabsorption;

* Cardiovascular diseases
* Vegetarian/vegan
* Smoking (to be included, subject has to stopped smoking at least 6 months for the start of the study)
* Usage of over the counter drugs, such as antacids and laxatives
* Abuse of drugs
* Consumption of >21 glasses of alcohol per week
* More than 5 hours of strenuous exercise (>6.0 METS) every week
* High level of restraint eating, as determined by the NVE questionnaire (Nederlandse vragenlijst voor eetgedrag)
* Claustrophobia
* Unsuitable veins for blood sampling
* Blood donation during the two months before the start of the study and during the study
* Current participation in other scientific studies
* Employee of Human and Animal Physiology or Human Nutrition or BSc/MSc thesis student at Human and Animal Physiology

Study design

Design

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):	28-03-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	19-02-2018

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

ID: 27539
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63894.081.17
OMON	NL-OMON27539