A study to evaluate the postprandial, short term effects of two baby nutrition products in adult, male volunteers

Published: 19-02-2014
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To investigate if the active product shows a postprandial plasma triglyceride profile different from the control product in healthy adult male volunteers.

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

Summary

ID

NL-OMON40343

Source
ToetsingOnline

Brief title
Postprandial effects of baby nutrition products

Condition

- Lipid metabolism disorders

Synonym
Increased triglyceride concentrations

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia
Source(s) of monetary or material Support: Nutricia Research

Intervention

Keyword: Baby nutrition, Postprandial, Triglycerides

Outcome measures

Primary outcome

Plasma triglyceride concentrations

Secondary outcome

Concentrations of free fatty acids, lipoproteins, glucose, insuline, amino

acids and satiety hormones.

Study description

Background summary

Breast milk is considered the gold standard of infant nutrition and differs from infant milk formula with respect to their fat globules. Breast milk contains larger fat globules which are coated by a phospholipid membrane, while milk proteins adhere to and cover the surface of fat globules in infant milk formula. The size and composition of these fat globules may have a beneficial effect on fat handling of the body. Nutricia Research has developed a milk formula with fat globules that resemble the fat globules present in breast milk. Research performed in animals provide strong arguments for the hypothesis that the size and composition of fat globules in nutrition affects digestion, absorption and plasma lipid compounds.

Study objective

To investigate if the active product shows a postprandial plasma triglyceride profile different from the control product in healthy adult male volunteers.

Study design

A randomised, double blind, cross-over study, which will consist of a screening and two testing days with 1 week wash-out in between. During the testing day, blood will be samples through an intravenous canula and subjects will be provided with a breakfast and a lunch.

Intervention

Subjects will be provided with two different milk powders dissolved in 400 mL water. These products are available in the supermarket or produced by Nutricia Research, and they are safe for human consumption.The content of protein, carbohydrates and fats is similar between the products, only the size and composition of the fat globules differs.

Study burden and risks

Subjects are screened for eligibility. During this screening visit, height, weight, waist circumference and blood pressure are determined. Subjects will also fill-out two questionnaires. During the study, subjects will come to the university twice for a testing dat of 5 hours. During this day, an intravenous canula is placed and blood will be sampled on 10 occasions. In addition, expired air is sampled on 6 time points and subjects will fill out satiety questionnaires on 6 time points. During the first testing day, subjects will also fill out a food frequency questionnaire.

Contacts

Public
Nutricia

Uppsalalaan 12
Utrecht 3584 CT
NL
Scientific
Nutricia

Uppsalalaan 12
Utrecht 3584 CT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Healthy, adult, male, Caucasian, Dutch-speaking subjects
- Non-smokers
- Lactose- and milk-tolerant
- Age 18-25 yr
- Body Mass Index (BMI) of 20-25 kg/m2
- Girth width <100 cm
- Stable body weight (weight gain or loss < 2 kg in the past three months)
- Willing to give up being a blood donor (or having donated blood) from 8 weeks before the start of the study, during the study, and 4 weeks after the study (i.e. after the follow-up phone call)
- Written informed consent

Exclusion criteria

- Top sports men or athletes with a daily strenuous training program (>2 hr)
- Known diseases or malfunctions e.g. fat malabsorption, gastrointestinal malformations, haemophilia, hepatitis B, human immunodeficiency virus (HIV), high blood-pressure, hyperlipidaemia or diabetes
- Current illnesses which could interfere with the study (e.g. prolonged severe diarrhoea, regurgitation, severe flu): to be determined on judgement of the investigator
- Medication use (except for paracetamol) or a medically prescribed diet
- More than 21 alcoholic consumptions per week
- Use of vitamin supplements, fish oil capsules or products rich in plant stanol or sterol esters during the study and 2 weeks in advance of study start
- Any current participation, or participation within 8 weeks before study start, in any other study involving investigational or marketed products
- Investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements and instructions

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	19-02-2014
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	NL46908.068.13