STRONG

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25466

Source
Nationaal Trial Register

Brief title
STRONG

Health condition

Healthy male volunteers.

Sponsors and support

Primary sponsor: University Maastricht
Department of Human Biology
Source(s) of monetary or material Support: Nutricia Research BV

Intervention

Outcome measures

Primary outcome

The primary outcome parameter in this study comprises the postprandial time course of plasma TG levels after ingestion of the active product vs. the control. Apart from plasma TG levels per se, either absolute (mM) or delta values, also the derivative AUC or iAUC are considered as primary outcome parameter.

Secondary outcome

Several plasma/serum parameters in response to ingestion of the active (and control) products are assessed.

Study description

Background summary

In this study standard infant formula containing a new fat blend is compared with standard infant formula without this containing the standard fat blend.
The main parameter being studied is the postprandial plasma triglyceride profile.
The study comprises two similar test days separated by > 5 days (wash out).
The 30 healthy volunteers enrolled are randomly allocated to consume these 2 study products in a randomised cross-over, double-blind, controlled manner (> 5 days between each session).

Study objective

The postprandial profile of plasma TG after ingestion of the active product is different to the control.

Study design

Time points of the outcome;
V-1 (pre-test period), V0 (screening, randomization, test day)
Wash out period of 5 days
V-1 (pre-test period), V0 (test day)
Follow up 2 weeks after final visit.

Intervention

Duration of intervention: 9-12 days, consisting of 2 test days within 2 weeks A follow up call will take place 2 weeks after the last test day.

Contacts

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Eligibility criteria

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)
- Written informed consent
- 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)

Exclusion criteria

-Top sports men or athletes with a daily strenuous training program (>2 hr/day)
-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 during the study
- 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

- More than 21 alcoholic consumptions per week

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-03-2014
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	10-03-2014
Application type:	First submission

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
NTR-new	NL4310
NTR-old	NTR4463
Other	METC azM : 133056

Study results