STRONG

Gepubliceerd: 10-03-2014 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25466

Bron
Nationaal Trial Register

Verkorte titel
STRONG

Aandoening

Healthy male volunteers.

Ondersteuning

Primaire sponsor: University Maastricht
Department of Human Biology
Overige ondersteuning: Nutricia Research BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	17-03-2014
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	10-03-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4310
NTR-old	NTR4463
Ander register	METC azM : 133056

Resultaten