Effects of stearidonic acid on serum triacylglycerol concentrations in overweight and obese subjects

Published: 23-06-2011
Last updated: 29-04-2024

To study the effects of echium oil, rich in SDA on serum triacylglycerol concentrations in healthy overweight and slightly obese men and women. The minor objective is to study the effects of echium oil on the omega-3 index, which is negatively...

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

Summary

ID

NL-OMON36066

Source
ToetsingOnline

Brief title
Stearidonic acid and lipid metabolism

Condition

- Lipid metabolism disorders

Synonym
hypertriglyceridemia / increased serum triacylglycerol concentrations

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Bioriginal Europe / Asia B.V., Bosland 40 3258 AC, Den Bommel, The Netherlands,Industrie

Intervention

Keyword: Lipid metabolism, n-3 polyunsaturated fatty acids, Serum triacylglycerol, Stearidonic acid

Outcome measures

Primary outcome

Main study parameters/endpoints: The main study parameter is the change is

fasting serum triacylglycerol concentrations.

Secondary outcome

The secondary endpoint is the change in the omega-3 index.

Study description

Background summary

Evidence exists that EPA (eicosapentaenoic acid or C20:5n-3) supplementation can reduce the risk for coronary heart disease. EPA can be synthesized from α-linolenic acid (ALA or C18:3n-3), but conversion is low. It has been suggested that the rate-limiting step for this conversion is the Δ6-desaturation of ALA into stearidonic acid (SDA or C18:4n-3). Thus, providing oils rich in SDA may increase the endogenous synthesis of EPA. This may subsequently lower serum triacylglycerol concentrations, an effect frequently observed after EPA supplementation, especially in people with increased triacylglycerol levels.

Study objective

To study the effects of echium oil, rich in SDA on serum triacylglycerol concentrations in healthy overweight and slightly obese men and women. The minor objective is to study the effects of echium oil on the omega-3 index, which is negatively related to cardiovascular risk and defined as the proportion of EPA and DHA in red blood cells.

Study design

Using a randomized, double-blind, placebo controlled crossover design, subjects will receive in random order for six weeks with a washout period of at least 14 days, daily 10 mL of echium oil or a high-oleic acid sunflower oil (HOSO) as

control.

Intervention

During the experimental period, subjects will receive daily one sachet at lunch and one sachet at dinner each providing 5 g of echium oil. During the control period, subjects will receive daily at the same time points sachets with the same amount of HOSO.

Study burden and risks

Before the start of the study subjects will be screened to determine eligibility during one 15 and one 10 min visit. During these visits, body weight, height and blood pressure will be measured and a blood sample (4.5 mL) will be drawn by means of venapunction. During the study, subjects will receive the echium and control in random order. At weeks 1, 3, 5 and 6 of each 6 wk period, a fasting blood sample will be drawn (10 mL, 20 mL and 2 x 30 mL). In addition, during week 6 of each intervention period, a retinal image will be taken and pulse wave velocity measurements will be performed to assess vascular function. Subjects will be asked to fill out a food frequency questionnaire two times and to keep a study-diary throughout study. On rare occasions, blood sampling might cause bruises or hematoma. Total time investment for the subjects will be approximately 6 hours.

Contacts

Public
Universiteit Maastricht

Postbus 616
6200 MD Maastricht
NL
Scientific
Universiteit Maastricht

Postbus 616
6200 MD Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- aged between 18-70 years
- Quetelet-index between 25-35 kg/m2
- mean serum triacylglycerol < 3.0 mmol/L

Exclusion criteria

- unstable body weight (weight gain or loss >2 kg in the past 3 months)
- indication for treatment with cholesterol-lowering drugs according to the Dutch Cholesterol Consensus
- use of medication or a diet known to affect serum lipid or glucose metabolism
- active cardiovascular disease like congestive heart failure or recent (<6 months) event (acute myocardial infarction, cerebro vascular accident)
- severe medical conditions that might interfere with the study such as epilepsy, asthma, chronic obstructive pulmonary disease, inflammatory bowel diseases and rheumatoid arthritis
- abuse of drugs
- more than 21 alcohol consumptions per week for men and 14 consumptions for women
- not or difficult to venipuncture as evidenced during the screening visits
- use of an investigational product within the previous 30 days
- not willing to stop the consumption of vitamin supplements, fish oil capsules or products rich in plant stanol or sterol esters 3 weeks before the start of the study
- not willing to give up being a blood donor (or having donated blood) from 8 weeks before the start of the study and during the study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2011
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

Date:	23-06-2011
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
ClinicalTrials.gov	NCT01365078
CCMO	NL36654.068.11