The effects of plant sterol and stanol esters on serum oxyphytosterol concentrations in healthy human subjects

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

Summary

ID

NL-OMON36657

Source
ToetsingOnline

Brief title
Phytosterols and oxyphytosterol concentrations

Condition

- Lipid metabolism disorders

Synonym
increased phytosterol concentrations

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: NWO

Intervention

Keyword: cholesterol, oxyphytosterols, phytosterols, postprandial metabolism

Outcome measures

Primary outcome

serum / plasma concentrations of plant sterols and oxyphytosterols,

Secondary outcome

Concentrations of lipoproteins, glucose, insulin, and markers reflecting

low-grade systemic inflammation and endothelial dysfunction.

Study description

Background summary

Plant sterols and stanols (also called phytosterols and phytostanols) are structurally related to cholesterol, but absorbed to a much lesser extent. Due to this structural similarity, plant sterols and stanols inhibit intestinal cholesterol absorption and lower serum LDL cholesterol concentrations by about 10% at daily intakes of 2.5 g. Plant sterol- and stanol-enriched food products are therefore widely available on the market to lower the risk for coronary heart disease. Like cholesterol, plant sterols undergo however oxidation, which results in the formation of oxyphytosterols. Animal studies have now suggested that oxyphytosterols are atherogenic. Although oxyphytosterols have been identified in human serum samples, the effect of an increased intake of plant sterols on serum oxyphytosterol concentrations in humans is not known. On the other hand, plant stanols cannot be oxidized and lower not only cholesterol absorption, but also plant sterol absorption.

Study objective

The major objective of the present study is to examine the effects of dietary plant sterols and stanols on fasting serum concentrations of oxyphytosterols. The minor objective is to investigate the effects of these products on postprandial serum oxyphytosterol concentrations.

Study design

A randomized, double-blind, placebo-controlled cross-over design. The total study duration will be 20 weeks, consisting of 3 test periods of 4 weeks in which the volunteers will use the investigational products. Each period will be separated by a wash-out period of 4 weeks. At the end of each test period, a postprandial test will be carried out.

Intervention

During each test period, the volunteers will consume 20 gram of a plant sterol-enriched margarine (providing daily 3.0 gram of plant sterols), a plant stanol-enriched margarine (providing daily 3.0 gram of plant stanols), or a control margarine. During the 4-week wash-out period, they will return to their normal eating habits. For the postprandial test, the subjects will consume a fat rich-test meal enriched with no or with 3.0 gram plant sterols or stanols at breakfast. In addition, a fat-rich lunch will be provided. Total follow-up during the postprandial period is 8 hours.

Study burden and risks

Blood samples will be drawn on 9 different occasions in a time frame of 20 weeks with a total amount of 514.5 mL. During the screening procedure 11 mL blood will be sampled. Furthermore, subjects will be asked to fill out a food frequency questionnaire three times at the end of each experimental period. Apart from a haematoma or bruise, which can occur during or after venipuncture, no side effects are expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

aged between 18 and 70 years
Body Mass Index (BMI) between 20-30 kg/m2
mean serum total cholesterol < 7.8 mmol/L
mean serum triacylglycerol < 3.0 mmol/L
mean plasma glucose < 6.1 mmol/L

Exclusion criteria

- unstable body weight (weight gain or loss > 3 kg in the past two months)
- active cardiovascular diseases like congestive heart failure or recent (<6 months) event (acute myocardial infarction, cerebral vascular incident)
- severe medical conditions that might interfere with the study such as epilepsy, asthma, chronic obstructive pulmonary disease, inflammatory bowel disease and rheumatoid arthritis)
- indication for treatment with cholesterol-lowering drugs according to the Dutch Cholesterol Consensus
- use of medication such as corticosteroids, diuretics or lipid lowering therapy
- abuse of drug or alcohol (>21 units per week)
- not willing to stop the consumption of vitamin supplements, fish oil capsules or products rich in sterol or stanol esters 4 weeks before the start of the study (wash-in period)
- use of an investigational product within another biomedical study within the previous month
- pregnant or breast-feeding women
- 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
- current smoker
- anemia. with a Hb-level below 7.5 mmol/L for men and below 7.0 mmol/L for women, as indicated by the blood bank of Maastricht

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2010
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO Date:	24-02-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-11-2011
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC 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	NL31083.068.09