The effects of consumption of vitamin E or lipoic acid on serum oxyphytosterol concentrations in subjects with impaired glucose tolerance or type II diabetes

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The major objective of the present study is to examine the effect of consuming vitamin E (804 mg) or lipoic acid (600 mg) for 4 weeks on fasting oxyphytosterol concentrations in subjects with impaired glucose tolerance or type 2 diabetes.

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

Summary

ID

NL-OMON39350

Source
ToetsingOnline

Brief title
Antioxidants and oxyphytosterol concentrations

Condition

- Lipid metabolism disorders

Synonym
increased phytosterol concentrations

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: NWO

Intervention

Keyword: Lipoic acid, Oxidative stress, Oxyphytosterols, Vitamin E

Outcome measures

Primary outcome

Blood samples will be drawn at week 1, 3 and 4 of each test period. The samples will be analysed for serum / plasma concentrations of plant sterols and oxyphytosterols.

Secondary outcome

Samples will also be analysed for oxidative stress markers, antioxidant capacity, lipoproteins, and for markers reflecting low-grade systemic inflammation and endothelial dysfunction.

Study description

Background summary

We now know that plant sterols can oxidize, which results in the formation of oxyphytosterols. Animal studies have suggested that oxyphytosterols are atherogenic components, however this relation has not yet been studied in humans. In our previous study (METC 09-3-088) we have shown in healthy volunteers that serum oxyphytosterol concentrations are linked to oxidative stress status (i.e. we were able to identify high and low sterol oxidizers). From the literature is known that especially type II diabetics and IGT subjects are characterized by increased oxidative stress markers and reduced antioxidant capacity. For this reason we also want to evaluate the oxyphytosterol concentrations in this population. Moreover, we know propose to evaluate the effect of antioxidant supplementation, i.e. vitamin E or lipoic acid, on serum oxyphytosterol concentrations in type II diabetic patients. If possible to lower oxyphytosterol concentrations in these populations this is obviously beneficial in case oxyphytosterols turn out to be atherogenic.

Study objective

The major objective of the present study is to examine the effect of consuming vitamin E (804 mg) or lipoic acid (600 mg) for 4 weeks on fasting oxyphytosterol concentrations in subjects with impaired glucose tolerance or type 2 diabetes.

Study design

The study design will be 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 subjects will use the investigational products. Each period will be separated by a washout period of 4 weeks.

Intervention

Subjects will be asked to consume three times daily control capsules, vitamin E capsules (total 804 mg) or lipoic acid capsules (total 600 mg) for three periods of four weeks. They will be asked to consume these capsules daily, divided over three eating moments. Each test-period is separated by a washout period of 4 weeks, during which the subjects will return to their normal patterns (indicating no vitamin supplementation). Of course they are not allowed to consume vitamin E or lipoic acid supplements during the washout periods. In total they will visit the department on 9 occasions to give a blood sample.

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 178.5 mL. During the screening procedure 9 mL (2x 3.5 ml, 1x 2.0 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 venepuncture, no side effects of the intervention itself 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 75 years
Body Mass Index (BMI) between 20-35 kg/m2
Mean serum total cholesterol <8.0 mmol/L
Mean serum triacylglycerol <3.0 mmol/L
Diagnosed with diabetes mellitus type 2 on a clinical basis or impaired glucose tolerance (defined as blood glucose >7.8 mmol/l and <11.0 mmol/L, two hours after ingesting 75 gram glucose in 150 ml water)

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
Use of medication such as corticosteroids, diuretics or lipid lowering therapy
Use of insulin therapy
Abuse of drugs or alcohol (>21 units per week)
Not willing to stop the consumption of vitamin supplements, containing lipoic acid and/or vitamin E, 1 month 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

Current smoker

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	07-09-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-11-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-07-2013
Application type:	Amendment

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	NL40392.068.12