The effects of a vitamin K-enriched dairy product on vitamin K-status and vascular health

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34582

Source
ToetsingOnline

Brief title
Nutrient enrichment for vascular health

Condition

- Other condition

Synonym
niet van toepassing

Health condition

preventie van hart-en vaatziekten

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Friesland Nutrition,VitaK BV

Intervention

Keyword: dairy vitamin K vascular health

Outcome measures

Primary outcome

The main parameters measured during the study are the undercarboxylated and carboxylated forms of the vitamin K-dependent proteins matrix-gla protein and osteocalcin.

Secondary outcome

The secondary study parameters are the levels of V-CAM, ICAM-1, E-selectin, SAA, sPLA-2, CRP, vWF, VEGF, IL-6, TNF-α, total cholesterol, triglycerides, and the lipoproteins HDL-cholesterol and LDL-cholesterol.

Study description

Background summary

Adequate nutritional intakes in the elderly supports general health and vascular health in particularly. However, the intake of specific nutrients has been regarded as suboptimal in older men and women, for instance intake of vitamin K and omega-3 fatty acids. Cardiovascular disease is the leading cause of morbidity and mortality in the western world. Healthy diet, including low fat dairy products, helps to maintain cardiovascular health. Supplementation of specific nutrients to a commercial standard dairy product may have extra beneficial effects.

Study objective

In this study, the beneficial effect of a nutrient enriched dairy product will be investigated on vascular health. To achive this benefit, the study product

contains extra vitamin K2 (selected for its protective role in vascular calcification) and omega-3 fatty acids (selected for risk reduction in atherosclerotic plaque formation) compared to basic dairy products. In addition, extra minerals and antioxidants have been added to the dairy product that may support general health.

Study design

A placebo-controlled randomized double-blind intervention study.

Intervention

The intervention in this study consists of daily consumption for 12 weeks of 2 basic yoghurt products (placebo group) or 2 nutrient-enriched yoghurt products (treatment group).

Study burden and risks

The risks for the subjects are minimal. No adverse effects are to be expected from the nutrient yoghurt enriched products. The subjects will visit the BioPartner Center six times for the screening, information-visit and consequent study visits and blood samplings at t=0, 4, 8 and 12 weeks. The major burden for the subjects consists of 5 venipunctures in 12 weeks. The venipunctures will be performed by experienced researchers.

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

Apparently healthy men and postmenopausal women between 45 and 65 years old
Subjects of normal body weight and height according to BMI between 23 and 30 kg/m2
Subjects of Caucasian race
Subject has given written consent to take part in the study
Low vitamin K-status

Exclusion criteria

Subjects with hypertension
Subjects with hypercholesterolemia
Subjects with (a history of) metabolic or gastrointestinal disease
Subjects presenting chronic degenerative and/or inflammatory disease
Subjects with (a history) of diabetes mellitus
Abuse of drugs and/or alcohol
Subjects receiving corticostero*d treatment
Subjects using oral anticoagulants and subjects with clotting disorders
Subjects using blood pressure lowering medication
Subjects using cholesterol-lowering medication
Subjects using vitamin K containing multivitamins or vitamin K supplements
Subjects consuming high amounts of vitamin K-containing food products
Subjects with cow*s milk allergy and lactose intolerance

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-09-2010
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	30-07-2010
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
CCMO	NL32434.068.10