Comparative study of three delivery systems of menaquinone-7

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To investigate the absorption of MK-7 from a nutrient-enriched dairy product compared to a general dairy product enriched with MK-7 and a MK-7 supplement.

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

Summary

ID

NL-OMON37333

Source
ToetsingOnline

Brief title
Comparative study menaquinone-7

Condition

- Other condition

Synonym
vitamin K deficiency, vitamin K insufficiency

Health condition

preventie van hart-en vaatziekten

Research involving
Human

Sponsors and support

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

Intervention

Keyword: dairy vitamin K absorption comparison

Outcome measures

Primary outcome

The circulating MK-7 levels will be measured at the various time-points (t = 0,

2, 4, 6 weeks) during intervention and the wash-out period (t= 3 days, 1 and 2

weeks) to determine the absorption profile of MK-7 within the dairy product.

Secondary outcome

The biochemical markers carboxylated MGP (cMGP), desphospho-uncarboxylated MGP

(dp-ucMGP), carboxylated osteocalcin (cOC) and uncarboxylated osteocalcin

(ucOC), will be measured at the various time-points (t = 0, 4, 6, 7 and 8

weeks) to determine the efficacy of the nutrient-enriched product vs. the other

2 products on MGP carboxylation status in the vessel wall and OC carboxylation.

Study description

Background summary

In an earlier study, beneficial effects of a nutrient-enriched dairy product on vitamin K-status were observed. The study product contained menaquinone-7 (MK-7) and omega-3 fatty acids for vascular health and extra minerals and antioxidants to support general health. It was the first time that such low dose of MK-7 (50 µg) could significantly improve vascular and general vitamin K-status already after short-term treatment. From the results of this study, it was assumed that the matrix of the dairy product and/or other components in the product, in which the vitamin was offered, contributed to optimal absorption and availability of vitamin K2. In this new study, the uptake and efficacy of MK-7 from the nutrient enriched product is investigated and compared to the uptake and efficacy from a MK-7-containing supplement and a basic dairy product enriched with MK-7.

Study objective

To investigate the absorption of MK-7 from a nutrient-enriched dairy product compared to a general dairy product enriched with MK-7 and a MK-7 supplement.

Study design

An open intervention study; 114 healthy men and postmenopausal women between 45 and 65 years will be recruited in the southern region of Limburg. Eligible participants will be randomly divided over three parallel study groups:
• Treatment group I: 38 subjects will receive daily a supplement consisting of 50 µg MK-7
• Treatment group II: 38 subjects will receive daily two basic dairy products enriched with MK-7 (50 µg)
• Treatment group III: 38 subjects will receive daily two nutrient-enriched dairy products (smart-mix) containing extra nutrients (calcium, magnesium, vitamin D3, vitamin C, MK-7 and omega-3 FA (fish-oil); all in a concentration of 15% of the recommended allowed daily intake (RDI)
The first blood sample will be taken after an overnight fast (t = 0 h) on the first test day. After the first blood sampling, participants start consuming the study products daily for an intervention period of 6 weeks followed by a 2-week wash-out period. During the intervention period, it is recommended that the two yoghurt products are consumed during the first part of the day, namely one product at breakfast and one product at lunch. Participants of the treatment group I are not allowed to consume their study product (MK-7 containing supplement) together with any milk-or yoghurt product. Subsequent blood samplings will take place at the following time-points: at t = 2, 4, and 6 weeks during intervention and t = 3 days, 1 and 2 weeks during the wash-out period.

Intervention

During the 6-wk intervention period, the subjects will be instructed to report any signs of illness, medication used, and any deviations from the study protocol. Subjects will be urged not to change their general dietary habits (except for vitamin K-containing products), smoking habits, level of physical exercise or use of alcohol during the study. Furthermore, the subjects will be instructed to keep a stable body weight; therefore body weight will be measured at the first and last study visit. In addition, two weeks (14 days) before the start of the study until the final blood sampling, participants will be asked to restrict their intake of vitamin K-containing foods, namely no curd products, maximum of 1 slice of cheese (25 g) per day and maximum of 200 gram of green vegetables. At each study visit, subjects will be questioned about their compliance with these restrictions and their answers will be recorded on a case report form (CRF). During the intervention period, also compliance of the treatment will be checked by questions at each study visit.

Study burden and risks

The risks for the subjects are minimal. No adverse effects are to be expected from the nutrient-enriched yogurt products. The subjects will visit the BioPartner Center Maastricht 8 times for the information-visit and consequent study visits and blood samplings at t=0, 2, 4 and 6 weeks, and at t=3 days, 1 and 2 weeks during the wash-out period. The major burden for the subjects consists of 7 venipunctures in 6 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 with body weight and height according to BMI between 23 and 30 kg/m2
Subject has given written consent to take part in the study

Subjects of Caucasian race

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 corticosteroid treatment
Subjects using oral anticoagulants and subjects with clotting disorders
Subjects using blood pressure-lowering medication
Subjects using cholesterol-lowering medication
Subjects using 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:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-04-2012
Enrollment:	114
Type:	Anticipated

Ethics review

Approved WMO Date:	28-03-2012
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	NL39841.068.12
Other	Wordt nog geregistreerd