The effect of vitamin K2 supplementation on cardiovascular risk markers.

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The main objective is to investigate whether and at what dose vitamin K2 increases carboxylation of MGP. Secondary objective is to investigate the effect of vitamin K2 on markers of CVD (osteocalcin, blood lipids, inflammatory factors and insulin...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON35262

Source
ToetsingOnline

Brief title
Vitamin K2 and CVD risk markers.

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
arteriosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: CVD, MGP, vitamin K

Outcome measures

Primary outcome

plasma concentrations of conformation-specific MGP (carboxylated and

undercarboxylated MGP)

Secondary outcome

blood lipid profile, inflammation markers, insulin sensitivity, adipokines and

osteocalcin carboxylation

Study description

Background summary

Vitamin K was mainly known for its function in blood coagulation, but recently its function in bone metabolism and vascular calcification became apparent. Vitamin K is a fat-soluble vitamin present in green vegetables in the form of vitamin K1 (phylloquinone) and as vitamin K2 (menaquinone) in animal products (meat, cheese). Vitamin K acts as a co-factor in the carboxylation of clotting factors, but also of other proteins in bone, osteocalcin (OC), and the vessel wall, matrix Gla-protein (MGP). MGP is a potent inhibitor of vascular calcification. Vitamin K can thus reduce vascular calcification and eventually cardiovascular disease (CVD) by carboxylation of MGP. Observational studies from our group have shown that a high vitamin K2 intake is associated with reduced coronary calcification and a reduced risk of coronary heart disease. These effects have been confirmed in randomized controlled trials among healthy volunteers. The effects of vitamin K2 are thought to be mediated by increased carboxylation of MGP. However, because conformation-specific analyses of MGP have not been available, the effect of vitamin K2 supplementation on carboxylation of MGP has not been examined. This study will investigate whether and at what dose vitamin K2 carboxylates MGP, using a novel ELISA assay to measure conformation-specific MGP. Preliminary studies have shown that vitamin K2 may also affect other cardiovascular risk factors such as blood lipid profile, inflammatory factors and insulin sensitivity. The effect of vitamin K2 supplementation on these markers will therefore be investigated as a secondary

objective.

Study objective

The main objective is to investigate whether and at what dose vitamin K2 increases carboxylation of MGP. Secondary objective is to investigate the effect of vitamin K2 on markers of CVD (osteocalcin, blood lipids, inflammatory factors and insulin sensitivity).

Study design

Double-blind, placebo-controlled, randomized trial (parallel design)

Intervention

The intervention period is 12 weeks.
Intervention group one receives a daily dose of 180 µg vitamin K2 (1 MK-7 capsule of 180 µg + one placebo)
Intervention group two receives a daily dose of 360 µg vitamin K2 (2 MK-7 capsules of 180 µg)
the placebo group receives daily a placebo (2 placebo capsules).

Study burden and risks

All participants will have to fill out small questionnaires at the start, during, and at the end of the study. They will fill in a 3-day food diary. There will be 3 site visits. During these visits we will take blood samples 35 ml each time). Further, participants have to take 2 capsules every day during 12 weeks.

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

-Men and women aged >= 40 and <= 65 years at Day 01 of the study
-Postmenopausal assessed by self-reported absence of menstrual periods for at least 1 year
-Body mass index (BMI) >= 18.5 and <= 30

Exclusion criteria

-Using vitamin K antagonists
-Using chronic medication for cardiovascular diseases (beta blockers, bloodthinner medication, rate control medication, cholesterol lowering medication, diuretics, vasodilators)
-For women: using menopausal hormone therapy
-having a known history with coagulation problems
-Smokers
-Using vitamin supplements that contain vitamin K, vitamin D or calcium
-A high vitamin K2 intake (>= 90 µg/day)
-Consuming natto
-Vegans
-Soy allergy

Study design

Design

Study phase: 2

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2010
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	21-05-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL29655.041.09