Vitamin K2 and CVD risk markers.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24375

Source
Nationaal Trial Register

Brief title
N/A

Health condition

cardio vascular disease, CVD, atherosclerosis

Sponsors and support

Primary sponsor: ?
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Outcome measures

Primary outcome

MGP levels in blood.

Secondary outcome

1. Blood lipid profile;

2. Inflammation markers;

3. Insulin sensitivity;

4. Adipokines;

5. Osteocalcin carboxlation.

Study description

Background summary

Rationale:

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 also 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.

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).

Study population:
60 Healthy human volunteers, 40-65 yr old.

Intervention:
The intervention period is 12 weeks. There are two intervention groups which will receive a daily dose of 180 µg or 360 µg vitamin K2 respectively. And there is one placebo group which receives placebo capsules daily.

Main study parameters/endpoints:

Plasma concentrations of conformation-specific MGP (carboxylated and undercarboxylated MGP).

Statistical analyses:

Differences between placebo and treated groups will be determined by ANOVA for repeated measurements.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

All participants will have to fill out small questionnaires at the start, during, and at the end of the study. There will be 3 site visits. During these visits we will take blood samples (25 ml each time) and during visit one there will be a physical examination. Further, participants have to take 2 capsules every day.

Study objective

Vitamin K2 can increase the carboxylation of the Matrix-Gla-Protein.

Study design

here is an intervention period of 12 weeks. At baseline, after 4 weeks and at the end of the intervention period (12 weeks) we will take bloodsamples of the subjects.

Intervention

The intervention period is 12 weeks. There are two intervention groups which will receive a

daily dose of 180 µg, or 360 µg vitamin K2 respectively. And there is one placebo group which receives placebo capsules daily.

Contacts

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Eligibility criteria

Inclusion criteria

1. Men and women age 40-65 years;

2. Postmenopausal assed by self-report;

3. BMI 18.5-30.

Exclusion criteria

1. Using vitamin K antagonists;

2. Using chronic medication for cardiovascular diseases for women;

3. Using menopausal hormone therapy;

4. Smokers;

5. Using vitamin supplements that contain vitamin K, vitamin D or calcium;

6. Consuming 5 or more than 5 portions of cheese per day;

7. Consuming 200 gram or more of soft curd cheese per day;

8. Consuming 200 gram or more green vegetables per day;

9. Consuming once or more than once a week goose liver;

10. Consuming natto;

11. Vegans;

12. Known soy allergy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-06-2010
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-09-2009
Application type:	First submission

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
NTR-new	NL1876
NTR-old	NTR1990
Other	METC UMC Utrecht : 09-270
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A