The VitaKids study: the effect of vitamin K supplementation on osteocalcin carboxylation in children.

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To study the effect of a vitamin K-containing food supplement on osteocalcin carboxylation in healthy children between 6 and 10 years of age in the Netherlands.

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

Summary

ID

NL-OMON30424

Source
ToetsingOnline

Brief title
VitaKids study

Condition

- Other condition
- Vitamin related disorders

Synonym
vitamin K deficiency in bone, vitamin K shortage in bone

Health condition

carboxylering van osteocalcine

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: children, osteocalcin, vitamin K

Outcome measures

Primary outcome

Undercarboxylated (ucOC) and carboxylated (cOC) fractions of osteocalcin (Takara, Japan) will be measured by enzyme-linked immunosorbent assay (ELISA). Both the ucOC fraction and the ucOC/cOC ratio (UCR) are sensitive indicators for the vitamin K status of bone. Elevated levels of UCR are indicative of an inferior vitamin K status of bone. The main study parameters are the mean percentages of change in serum undercarboxylated osteocalcin (ucOC) and UCR from baseline (t=0) to endpoint (t=8 weeks) in both treatment groups.

Secondary outcome

The secondary end points are the percentages of change in serum vitamin K levels in relation to lipid metabolism markers from baseline to endpoint in each individual.

Furthermore, the percentages of changes in serum BAP and NTX from baseline to endpoint in each individual are considered to be endpoints as well.

Study description

Background summary

Results from several studies show that vitamin K has an important function in

bone metabolism. In a previous cross-sectional study conducted by our department, evidence for a poor vitamin K status of bone during growth in children was found (unpublished data, submitted Pediatric Research, May 2006). These findings justify clinical intervention studies in which bone quality is monitored as a function of long-term vitamin K-supplementation. Before a long-term intervention study is undertaken, it is important to determine the effect of vitamin K administration on osteocalcin carboxylation in this specific population. Although the relationship between increased vitamin K intake and osteocalcin carboxylation was already clearly demonstrated in several adult groups (e.g. healthy adults, postmenopausal women), this has never been shown in children.

Study objective

To study the effect of a vitamin K-containing food supplement on osteocalcin carboxylation in healthy children between 6 and 10 years of age in the Netherlands.

Study design

Randomised double-blind placebo-controlled intervention study.

Intervention

The subjects are randomised into two groups:
- placebo group: during 8 weeks, 20 children will receive one tablet of placebo- food supplement per day
- treatment group: during 8 weeks, 20 children will receive one tablet of food supplement per day containing 45 µg vitamin K2.

Study burden and risks

This short intervention study will be performed in healthy children because previous study results show evidence for a poor vitamin K status of bone in this subject population. The relationship between increased vitamin K intake and osteocalcin carboxylation has not yet been demonstrated in this group. The burden for the subjects consists of blood sampling at start and end of study, preferably in a fasting condition. During 8 weeks, they will ingest a food supplement daily. The intake of the food supplement will be recorded on a special vitamin K-calendar by the child, with help of the parents. Three visits will be planned. The first visit comprises a short physical examination (length, weight) and a short questionnaire about food habits.
The risks for the subjects are minimal. No adverse effects are to be expected. The benefit for subjects in the treatment group is adequate dietary suppletion of vitamin K for 8 weeks

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Healthy male and female children between 6 and 10 years of age.
- Subjects of normal body weight and height (p3-p97) according to standard Dutch growth charts

Exclusion criteria

- Subjects with (a history of) metabolic or gastrointestinal disease
- Subjects with (a history of) soy allergy
- Subjects presenting chronic inflammatory disease
- Subjects receiving cortico*d treatments
- Subjects using oral anticoagulants

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2007
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	19-10-2006
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	30-11-2006
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL14210.000.06