

# Evaluation of the Clinical use of vitamin K supplementation in post-menopausal women with Osteopenia

**Submission date**  
11/08/2004

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
09/09/2005

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
21/03/2016

**Condition category**  
Musculoskeletal Diseases

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00150969

## Secondary identifying numbers

MCT-50422

# Study information

## Scientific Title

Evaluation of the clinical use of vitamin K supplementation in post-menopausal women with osteopenia: a randomised controlled trial

## Acronym

ECKO

## Study objectives

Vitamin K1 supplementation of 5 mg daily over 2 years can decrease the rate of bone loss in post-menopausal women with osteopenia.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

University Health Network Research Ethics Board, Toronto, 22/01/2002

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Osteopenia/osteoporosis

## Interventions

Calcium and vitamin D supplementation plus 5 mg vitamin K1 or placebo daily for 2 years.

## Intervention Type

Supplement

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Vitamin K

**Primary outcome measure**

Differences in the percent change in Bone Mineral Density at the spine (L1 - L4) and the total hip between treatment and placebo groups measured yearly

**Secondary outcome measures**

1. Determining potential adverse effects from long-term vitamin K1 supplementation
2. Whether vitamin K1 supplementation affects levels of bone formation markers (serum osteocalcin [OC] and serum bone specific alkaline phosphatase [BAP]) and bone resorption markers (serum N-telopeptide [NTx])
3. Whether vitamin K1 supplementation affects the degree of carboxylation of OC, a major vitamin K-dependent protein in bone
4. Whether vitamin K1 supplementation affects health-related quality of life
5. Whether vitamin K1 supplementation decreases risk of having fragility fractures
6. Whether Apo E modulates the effect of vitamin K1 on bone

**Overall study start date**

01/01/2002

**Completion date**

31/08/2006

## **Eligibility**

**Key inclusion criteria**

1. Post-menopausal women with osteopenia
2. Lowest bone mineral density at the total hip, femoral neck and lumbar spine (L1 - L4) between -1.0 and -2.0
3. Post-menopausal defined as one year since the natural cessation of menses, or hysterectomy with either post-menopausal status confirmed by follicle stimulating hormone (FSH) laboratory values, or age 55 and above
4. Osteopenic T-score between -1 and -2 on lumbar, total hip or femoral neck bone mineral density (BMD) measurement. Based on documented BMD done within the past 6 months or BMD measurement done at screening.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

**Key exclusion criteria**

1. Women ever having had a fragility fracture after the age of 40
2. Women currently on anticoagulants, previously on anticoagulants in the past 3 months, or expected to be on anticoagulants in the near future
3. Women on hormone replacement therapy, raloxifene, bisphosphonates or calcitonin during the past 3 months
4. Women who have ever been on a bisphosphonate for more than 6 months
5. Women previously diagnosed with Pagets disease, hyperparathyroidism, hyperthyroidism or other metabolic bone diseases
6. Women with decompensated diseased of the liver, kidney, pancreas, lung or heart; Women with a history of active cancer within the past 5 years
7. Women taking mega-doses of vitamin A (more than 10,000 IU per day) or E (more than 400 IU per day)
8. Women involved in other clinical trials
9. Poor medical or psychiatric risk for the study

**Date of first enrolment**

01/01/2002

**Date of final enrolment**

31/08/2006

**Locations****Countries of recruitment**

Canada

**Study participating centre**

Toronto General Hospital

Toronto

Canada

M5G 2N2

**Sponsor information****Organisation**

University Health Network, Toronto (Canada)

**Sponsor details**

200 Elizabeth Street

7 Eaton North - 221

Toronto, Ontario

Canada

M5G 2C4

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carolynm@uhnresearch.ca

**Sponsor type**

University/education

**Website**

<http://www.uhnresearch.ca>

**ROR**

<https://ror.org/026pg9j08>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Canadian Institutes of Health Research (ref: MCT-50422)

**Alternative Name(s)**

Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR\_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Canada

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>				No	No
<a href="#">Results article</a>	results	14/10/2008		Yes	No