

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	<input type="checkbox"/> Prospectively registered
Registration date 09/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/03/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00150969

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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 disease 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)

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, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/10/2008		Yes	No
Basic results				No	No