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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 [ ] Statistical analysis plan [X] Results [ ] Individual participant data
Registration date 09/09/2005	**Overall study status** Completed	
Last Edited 21/03/2016	**Condition category** Musculoskeletal Diseases	

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteopenia/osteoporosis

Interventions
Calcium and vitamin D supplemenation 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 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)

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