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Effect of combined exercise therapy and isoflavone supplementation on prevention of osteoporosis

Submission date 09/09/2005	**Recruitment status** No longer recruiting
Registration date 09/09/2005	**Overall study status** Completed
Last Edited 01/02/2019	**Condition category** Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00204425

Secondary identifying numbers
MCT-68095

Study information

Scientific Title
Effect of combined exercise therapy and isoflavone supplementation on prevention of osteoporosis: a randomised controlled trial

Study objectives
Exercise training and isoflavone supplementation will be additive for increasing bone mineral density.

Please note that as of 06/03/2009 the anticipated end date in this record was amended; the initial end date at the time of registration was 01/12/2007.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Saskatchewan Biomedical Research Ethics Board (Bio-REB) gave approval on the 1st August 2003

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

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

Interventions
Group 1: exercise training plus isoflavone placebo
Group 2: exercise training placebo (flexibility program) plus isoflavone therapy
Group 3: exercise training plus isoflavone therapy
Group 4: exercise training placebo plus isoflavone placebo

The exercise training intervention will consist of weight training combined with walking. The exercise training placebo will consist of home-based flexibility program (a type of training that has no effect on bone mineral). All participants will be required to fill out and return to the study staff daily activity logs throughout the study.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Lumbar spine bone mineral density

Secondary outcome measures
1. Bone mineral density of the proximal femur and whole body
2. Bone quality of the calcaneus
3. Geometry the proximal femur
4. Lean tissue mass
5. Fat mass
6. Body mass index
7. Waist girth
8. Skinfolds
9. Blood lipids
10. Breast density
11. Endometrial thickness
12. Menopausal symptoms
13. Physical activity levels
14. Muscular strength
15. Self-paced walking ability
16. Balance and flexibility

Overall study start date
14/09/2004

Completion date
30/05/2008

Eligibility

Key inclusion criteria
Post-menopausal women (age range of approximately 45 to 70 years)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
360 (351 at end of recruitment)

Key exclusion criteria
1. Diagnosed osteoporosis
2. Previous fragility fractures
3. Above normal bone mineral density (equal to or above the young adult mean)
4. Breast or endometrial cancers
5. Women taking bisphosphonates, hormone replacement therapy, selective estrogen receptor modulators, parathyroid hormone (PTH), or calcitonin in the past 12 months
6. Taking corticosteroids or diuretics
7. Diagnosed Crohns Disease and Cushing Disease
8. Women with allergies to soy
9. Severe osteoporosis
10. Smokers
11. Currently participating in vigorous exercise programs

Date of first enrolment
14/09/2004

Date of final enrolment
30/05/2008

Locations

Countries of recruitment
Canada

Study participating centre
University of Saskatchewan
Saskatoon
Canada
S7N 5B3

Sponsor information

Organisation
University of Saskatchewan (Canada)

Sponsor details
105 Administration Place
Saskatoon
Canada
S7N 5A2

Sponsor type
Not defined

Website
http://www.usask.ca/

ROR
https://ror.org/010x8gc63

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-68095)

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?
Results article	results	01/04/2013	01/02/2019	Yes	No