

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

Submission date 09/09/2005	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 01/02/2019	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

Contact name

Dr Philip David Chilibeck

Contact details

University of Saskatchewan
College of Kinesiology
87 Campus Drive
Saskatoon
Canada
S7N 5B3
+1 306 343 6577
phil.chilibeck@usask.ca

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