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# Bone and muscle structure and function in relation to exercise and oestrogen replacement

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 11/06/2009 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 09/07/2009 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 09/07/2009 | Musculoskeletal Diseases | |

**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**

**Secondary identifying numbers**
N/A

## Study information

**Scientific Title**

Bone and muscle structure and function in relation to exercise and oestrogen replacement: a randomised double-blind placebo-controlled one-year-trial

## Acronym
Ex/HRT-study

## Study objectives
Deterioration of bone and muscle properties may occur after menopause. High-impact, power training and oestrogen-containing hormonal replacement therapy (HRT) may reverse these deteriorations. Combined treatments with both training and HRT may have additional effects.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethical Committee of the Central Hospital of Central Finland has approved this study on 11th June 1996 (ref: Dnro1053/04/046/06). The study was re-evaluated concerning the use of DNA-samples and approved on the 18th October 2005.

## Study design
Randomised double-blind placebo-controlled one-year-trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## 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, sarcopenia

## Interventions
Exercise (Ex): 1-year progressive physical training programme that included a supervised circuit training session twice a week and a series of exercises at home 4 days per week. Training was high-impact power training consisting of circuit training periods for 8 - 11 weeks, interrupted by three high-impact aerobic dance periods for 2 weeks and a summer pause for 5 weeks. They also used placebo tablets.
HRT: the combined oestradiol (2 mg) and noretisterone acetate (1 mg) product (Kliogest®, Novo Nordisk) was administered continously, one tablet per day for one year. The administration of HRT was conducted double-blinded.
Ex+HRT: participants conducted the training program and used HRT.

CO: control arm participants did not recieve any treatment, but they used placebo and were asked not to change their daily physical activities.

Total duration of the treatment was 12 months; the 12-month measurements were performed within a week of ending the treatments. This part of the trial was completed on the 30th August 1997.

A 10-year follow-up measurement was also performed for the participants who were willing to come back to the lab (n = 47). These measurements were performed from the 15th September to 24th November 2007. End of analysis and follow-up will be on the 31st December 2013.

## Intervention Type
Drug

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Oestradiol, noretisterone acetate (Kliogest®)

## Primary outcome measure
1. Developing methods for the testing of material and structural changes in the trabecular and cortical bone sites of the lower leg in relation to high-impact exercise and hormone replacement:
1.1. Single photon absorption method
1.2. Computed tomography
1.3. Elastic wave propagation
1.4. Ultrasonography
2. The effects of a high-intensity, explosive-type physical training and hormonal replacement on lower leg muscle mass, structure and performance in post-menopausal women:
2.1. Ultrasonography
2.2. Computed tomography
2.3. Muscle biopsies
2.4. Maximal isometric strength measurements with dynamometer chair
2.5. Measurement of explosive muscle power; ability to elevate the body's centre of gravity during vertical jumps onto a contact mat
2.6. Muscle performance; maximal running speed over 20 m distance

All measurements were done at baseline (0 months), at mid-point (6 months) and after completion of the treatments (12 months).

## Secondary outcome measures
1. Examining the molecular mechanism responding to high-intensity, explosive-type physical training and hormonal replacement by using muscle biopsies, taken at baseline, after 0.5 years of study onset and after 1 year of study onset, by microarray and other applicable molecular methods
2. Examining the adaptation of bone collagen metabolism and the different types of muscle fibres to altered force transmission and oestrogen status (using serum and urine samples to determine the content of deoxypyridinoline in overnight (10 hour) samples and using immunohistochemical methods with respective antibodies

All measurements were done at baseline (0 months), at mid-point (6 months) and after completion of the treatments (12 months).

### Overall study start date
01/09/1996

### Completion date
31/12/2013

## Eligibility

### Key inclusion criteria
1. No serious medical conditions
2. No current or previous use of medications including oestrogen, fluoride, calcitonin, biophosphonates or steroids
3. Last menstruation at least 0.5 years but not more than 5 years ago
4. Follicle-stimulating hormone leves greater than 30 iu/litre
5. No contra-indications for exercise and HRT
6. Aged 50 - 57, caucasian post-menopausal women

### Participant type(s)
Patient

### Age group
Adult

### Sex
Female

### Target number of participants
80

### Key exclusion criteria
1. Serious medical conditions
2. Current or previous use of medications including oestrogen, fluoride, calcitonin, biophosphonates or steroids
3. Currently menstruating or having last menstruation within 0.5 years of the onset of study or longer than 5 years ago
4. Follicle-stimulating hormone leves less than 30 iu/litre
5. Contra-indications for exercise and HRT

### Date of first enrolment
01/09/1996

### Date of final enrolment
31/12/2013

## Locations

**Countries of recruitment**
Finland

**Study participating centre**
**PO Box 35**
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# Sponsor information

**Organisation**
University of Jyvaskyla (Finland)

**Sponsor details**
Department of Health Sciences
P.O.Box 35
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**Sponsor type**
University/education

**Website**
http://www.jyu.fi/

**ROR**
https://ror.org/05n3dz165

# Funder(s)

**Funder type**
Government

**Funder Name**
Finnish Academy (Finland) - 1st January 1996 - 1st January 2001

**Funder Name**

Finnish Funding Agency for Technology and Innovation (TEKES) (Finland) - 1st January 1996 - 1st January 2001

### Funder Name
Finnish Ministry of Education (Finland) (ref: 98/772/2002)

# 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 | ultrasound and bone mineral density assessment results | 01/06/1999 | | Yes | No |
| Results article | developing methods for assessing changes in bone results | 01/07/2000 | | Yes | No |
| Results article | initial results | 01/08/2001 | | Yes | No |
| Results article | bone mass distribution results | 01/07/2002 | | Yes | No |
| Results article | developing methods for testing the material changes and turnover in bone results | 01/07/2002 | | Yes | No |
| Results article | lower-body muscle power results | 01/06/2004 | | Yes | No |
| Results article | muscle attenuation results | 01/09/2005 | | Yes | No |
| Results article | muscular transcriptome results | 01/12/2007 | | Yes | No |