Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of Aerobic and Strengthening Exercises on Balance, Muscle Strength and Bone Density among the Post Menopausal Women with Osteopenia and Osteoporosis

Protocol summary

Summary

The purpose of present trial is to investigate the effect of exercise therapy on osteoporosis. 90 postmenopausal osteoporotic women referred to the physical medicine and rehabilitation clinic are randomized into three groups of 30 people. Then, drug therapy; including alendronate, calcium, and vitamin D is begun in all three groups. In the second and third groups, different exercises are also applied in addition to medication. In the second group, aerobic exercise, including walking on the treadmill and stationary cycling, and in the third group isotonic and isometric strengthening exercises of trunk and hip and knee muscles, are conducted for 9 months with three months relative resting phase.In other words our sports therapy program was over ally included six month exercise accompany with three month home-based exercises within therapy periods. Before treatment, quadriceps muscles strength, hip abductors and extensors of trunk are determined by MMT. To measure the balance status, fall risk and postural stability indices are determined using Biodex balance training instrument. Bone density of lumbar and femoral neck areas are measured by DEXA method and T-score is determined. Finally, SF36 questionnaire of "quality of life" is completed by the patients. The above-mentioned check-ups will be repeated and compared again after 6 months in all three groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008153217N2**
Registration date: **2010-09-14, 1389/06/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-09-14, 1389/06/23

Registrant information

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Recruitment status

Recruitment complete

Funding source

Research Chancellor of Tabriz University of Medical Sciences

Expected recruitment start date

2009-11-22, 1388/09/01

Expected recruitment end date

2010-11-22, 1389/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Aerobic and Strengthening Exercises on Balance, Muscle Strength and Bone Density among the Post Menopausal Women with Osteopenia and Osteoporosis

Public title

Exercise therapy on osteoporosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:post menopausal women with severe osteopenia and osteoporosis (T-score<-2.5). Exclusion Criteria : presence of severe cardiovascular disease, severe joint degenerative diseases or severe musculoskeletal disorders and performing physical activities other than our prescribed exercise programs.

Age

From **47 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Chancellor of Tabriz University of Medical Sciences

Street address

Research Chancellor-3rd floor-Central building number 2-Tabriz University of Medical Sciences-Golgasht Avenue-Tabriz

City

Tabriz

Postal code

51656

Approval date

2009-03-29, 1388/01/09

Ethics committee reference number

141/4/5

Health conditions studied

1

Description of health condition studied

Post menopausal osteoporosis

ICD-10 code

M81.0

ICD-10 code description

Post menopausal osteoporosis without fracture

Primary outcomes

1

Description

Bone Mineral Density (BMD)

Timepoint

before intervention and 6 months after intervention (immidiately after termination of treatment)

Method of measurement

using Dual Energy X-ray Absorbtiometry (DEXA) with measurment of T-score

2

Description

Time up & go (TUG)

Timepoint

before intervention and 6 months after intervention (immidiately after termination of treatment)

Method of measurement

using chronometer this six meter distance is measured by seconds.

3

Description

Fall risk

Timepoint

before intervention and 6 months after intervention (immidiately after termination of treatment)

Method of measurement

using Biodex balance training is measured and because it is a relative value,it has not special unit.

4

Description

Postural Stability

Timepoint

before intervention and 6 months after intervention (immidiately after termination of treatment)

Method of measurement

using Biodex balance training is measured and because it is a relative value,it has not special unit.

5

Description

Muscle Strength

Timepoint

before intervention and 6 months after intervention (immidiately after termination of treatment)

Method of measurement

It is evaluated via manual muscle testing(MMT) in physical examination.This relative indicator is measured between 1/5 to 5/5.

Secondary outcomes

1

Description
Quality of life
Timepoint
before intervention and 6 months after intervention (Immediately after treatment)
Method of measurement
This variable is measured using SF36 Questionnaire with scoring between 0 to 100.

2

Description
Body Mass Index (BMI)
Timepoint
before intervention and 6 months after intervention (Immediately after treatment)
Method of measurement
BMI is measured by body composition test instrumentation and its unit is Kg/m2.

Intervention groups

1

Description
Drug therapy, including alendronate, calcium and vitamin D in control groups
Category
Treatment - Drugs

2

Description
Drug therapy, including alendronate, calcium and vitamin D as well as Aerobic exercises including three steps;warm up for 10 minutes,walking on treadmill with 60-80% of maximum heart rate and stationary cycling for 30 minutes and finally cooling down for 5 minutes following by relaxation and stretching exercises are performing.Each interventional group is including 10-15 patients and these exercises are conducted for 6 months with one month resting.
Category
Rehabilitation

3

Description
Drug therapy, including alendronate, calcium and vitamin D as well as Strengthening exercises for trunk extensors,hip abductors and knee extensors or quadriceps muscles initially Isometric and then Isotonic; against resistence are performing.Each interventional group is including 10-15 patients and these exercises are conducted for 6 months with one month resting phase.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Educational and Treatment center
Full name of responsible person
Maryam Ariajoo
Street address
Physical Medicine & Rehabilitation Ward, Shahid Madani Hospital, Daneshgah Ave.
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Sponsors / Funding sources

1

Sponsor
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Research Chancellor of Tabriz University of Medical Sciences
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Research Chancellor-3rd floor-Central building number 2-Tabriz University of Medical Sciences-Golgasht Avenue-Tabriz
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Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Chancellor of Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty