

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name

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Name of organization / entity

Tabriz University of Medical Sciences

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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-
Goltasht 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
(immediatly 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
(immediatly 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
(immediatly 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
(immediatly 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
(immediatly 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 resistance 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 Ariafoo

Street address

Physical Medicine & Rehabilitation Ward, Shahid Madani Hospital, Daneshgah Ave.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Chancellor of Tabriz University of Medical Sciences

Full name of responsible person

Azam Safi

Street address

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

City

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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

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Jalil Toofan

Position

Physician, Resident of Physical medicine and Rehabilitation

Other areas of specialty/work**Street address**

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Full name of responsible person

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Position

Assistant professor of Physical Medicine & rehabilitation

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Web page address**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