

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effects of Application of Pulsed Electromagnetic Field and Therapeutic Exercise on Bone Mineral Density and Metabolism, and Quality of Life in Postmenopausal Osteoporotic Women

Protocol summary

Study aim

The purpose of this research is to investigate and compare three types of therapeutic intervention, pulsed electromagnetic field, therapeutic exercise and combined exercise therapy and pulsed electromagnetic field on bone mineral density, bone metabolism and quality of life in patients with osteoporosis

Design

Single-blinded Randomized control trial with parallel groups and 12-week follow-up. Randomization will be done by selecting the sealed envelope. The sample size will be 12 people in each group according to the similar studies and using G-power software.

Settings and conduct

After the initial evaluation, the patients who meet the inclusion criteria will be randomly assigned to one of the three groups of pulsed electromagnetic field, therapeutic exercise, combined treatment of pulsed electromagnetic field and therapeutic exercise. Twice a week for 12 weeks and the evaluation will be done after the end of 12 weeks and also after the 12-week follow-up.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: women aged 55 and 68 with a diagnosis of osteoporosis by a rheumatologist, 6 months have passed since menopause, have no history of ovariectomy or fracture due to osteoporosis. Exclusion criteria: - a history of using drugs affecting bone metabolism, or sedatives, or doing physical therapy and hormone therapy in the last 6 months - unwillingness to Continuation of the treatment or change in the sample conditions that cause the loss of one of the entry conditions

Intervention groups

Pulsed Electromagnetic field 24 intervention sessions (2 times a week) - Exercisetherapy group 24 intervention sessions (2 times a week) - combined treatment of Pulsed Electromagnetic field and Exercise therapy 24

sessions (2 times a week)

Main outcome variables

Bone Mineral Density-Bone Metabolism-Quality of Life

General information

Reason for update

Acronym

PEMF

IRCT registration information

IRCT registration number: **IRCT20221202056687N1**

Registration date: **2022-12-15, 1401/09/24**

Registration timing: **prospective**

Last update: **2022-12-15, 1401/09/24**

Update count: **0**

Registration date

2022-12-15, 1401/09/24

Registrant information

Name

Fatemeh Sangtarash

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of Application of Pulsed Electromagnetic Field and Therapeutic Exercise on Bone Mineral Density and Metabolism, and Quality of Life in Postmenopausal Osteoporotic Women

Public title
"Effect of Pulsed Electromagnetic Field and Exercise Therapy in treatment of Osteoporosis"

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 women at the age of 55-68, having reached menopause at least 5 year before the study. A body mass index of 22-30 T-score for the hip or lumbar spine -2.5 SD or less. do not have a history of overioectomy syrgery Do not have a history of osteoporosis fracture
Exclusion criteria:
 Participating in sports regularly for at least one year before starting the study (regular exercise means at least 30 minutes a day and 3 days a week) Taking drugs that affect bone metabolism, except for daily calcium and vitamin D and weekly alendronite tablets, which will be prescribed by the rheumatology consultant of the study with the same dose for all participants. The presence of any medical problem affecting the person's movement (diabetes - diseases of the vestibular system - uncorrected vision or hearing disorders - neurological diseases A history of surgery in the spine and pelvis and the use of tools to fix it or a history of surgery in the lower limbs • History of hormone therapy in the last 6 months A history of having cardiovascular diseases, such as uncontrolled blood pressure, which will be considered as an exclusion criterion for groups that will do exercise therapy Using physiotherapy modalities effective on bone metabolism, such as using WBV, LPL, PEMF modalities in the last 6 month Using tranquilizers (Tranquillizer) in both minor classifications (anti-anxiety, diazepam, oxazepam, alprazolam, etc.) and major (antipsychotic drugs such as haloperidol, phenotazines, fluphenazine, etc.) in three last month Unwillingness of the samples to continue the treatment and not participating regularly in the treatment program A change in sample conditions that would result in missing one of the inclusion criteria

Age
From **55 years** old to **68 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomly assign patients, sealed envelopes containing the words "pulsed electromagnetic field" or "therapeutic exercise" or "combination of pulsed electromagnetic field + therapeutic exercise" will be prepared. After flipping the cards, the clinic secretary clinic will randomly select one of the envelopes for each patient. The use of this method guarantees randomization.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is single-blinded study, which means that an experience physiotherapist do the intervention and another physiotherapist will do the evaluations. As a result, the evaluator will not know which group the patient belongs to.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
Secondary trial Id
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Faculty of Rehabilitation Sciences, Enghelab St., Tehran
City
Tehran
Province
Tehran
Postal code
1148965111
Approval date
2022-12-11, 1401/09/20
Ethics committee reference number
IR.TUMS.FNM.REC.1401.126

Health conditions studied

1

Description of health condition studied

Osteoporosis

ICD-10 code

M81.0

ICD-10 code description

Age-related osteoporosis without current pathological fracture

Primary outcomes

1

Description

Bone mineral Density

Timepoint

At the beginning of the intervention and 12 weeks after the end of the intervention

Method of measurement

The use of X-Ray absorption method with dual energy DXA will be measured using the HOLOGENIC QDR1000 device

2

Description

Bone Turnover markers-bone specific alkaline phosphatase(BSALP)

Timepoint

Before the start of the intervention - immediately after the end of the intervention - after a 12-week follow-up from the end of the intervention

Method of measurement

Blood test and examination of blood sample with the laboratory method of ELISA

3

Description

Bone Turnover markers-N- terminal telopeptide of type 1 collagen

Timepoint

Before the start of the intervention - immediately after the end of the intervention - after a 12-week follow-up from the end of the intervention

Method of measurement

Blood test and examination of blood sample with the laboratory method of ELISA

4

Description

Quality of life

Timepoint

Before the start of the intervention - immediately after the end of the intervention - after a 12-week follow-up from the end of the intervention

Method of measurement

Quality Of Life Questionnaire Of European Foundation for Osteoporosis

Secondary outcomes

1

Description

Thoracic kyphosis

Timepoint

before and after the intervention (12 weeks later) ,and 12 weeks follow up after the end of the intervention

Method of measurement

Photogrammetry method

2

Description

lumbar lordosis

Timepoint

before and after the intervention (12 weeks later) ,and 12 weeks follow up after the end of the intervention

Method of measurement

Photogrammetry method

3

Description

Functional Balance

Timepoint

before and after the intervention (12 weeks later) ,and 12 weeks follow up after the end of the intervention

Method of measurement

Functional balance study with Timed Up and Go (TUG), Unilateral Stance Test(USL)

4

Description

Muscle Strength

Timepoint

before and after the intervention (12 weeks later) ,and 12 weeks follow up after the end of the intervention

Method of measurement

Using micro manual muscle tester

5

Description

fear of falling

Timepoint

before and after the intervention (12 weeks later) ,and 12 weeks follow up after the end of the intervention

Method of measurement

Persian version of Falls Efficacy Scale-International Questionnaire

Intervention groups

1

Description

Intervention group: Pulse Electro Magnetic field

Category

Rehabilitation

2

Description

Intervention group: Exercise therapy

Category

Rehabilitation

3

Description

Intervention group: Pulsed Electromagnetic field+Exercise therapy

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Jaliasr Hospital, Zanzan

Full name of responsible person

Alireza Sadeghi

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2

Recruitment center

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar fotohi

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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

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Azadeh Shadmehr

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Position

student

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

If needed by the researchers and their request, the raw data of the research and its analysis will be provided to researchers

When the data will become available and for how long

After the publication of the articles resulting from the research

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

The data is only available to other researchers to study and review treatment results Placed

From where data/document is obtainable

By sending an email to the corresponding author

What processes are involved for a request to access data/document

Send an email to the responsible author and request the document

Comments