

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Evaluation of the effect of dynamic hyperextension brace on osteoporosis and kyphosis reduction in postmenopausal osteoporotic women

Protocol summary

Summary

Objectives: Evaluation of the effect of dynamic hyper extension brace on the reduction of kyphosis and osteoporosis in postmenopausal osteoporotic women. Design: Randomized controlled trial. Setting and conduct: A total of 60 postmenopausal osteoporotic women will be randomly assigned to the case and control group. Inclusion criteria: Female; postmenopausal; osteoporosis; Kyphosis; Exclusion criteria: Patients having metabolic or hormonal disorders affecting the skeletal structure; patients receiving drugs with known affect on bone metabolism; patients currently receiving osteoporosis treatment; patients not able to use brace; Interventions: A 600000 unit intramuscular vitamin D and 35 mg/ week oral alendronate will be administered for control group. The case group was additionally intervened by the application of Dynamic hyper extension brace containing one kilogram weight, and asked to use the brace 12 hours a day in their daily activities . Main outcome measures: osteoporosis; kyphosis.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016111430871N2**

Registration date: **2016-12-13, 1395/09/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-12-13, 1395/09/23

Registrant information

Name

Alireza Mirzaei

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of dynamic hyperextension brace on osteoporosis and kyphosis reduction in postmenopausal osteoporotic women

Public title

The effect of brace on osteoporosis and kyphosis reduction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Female; postmenopausal; osteoporosis; Kyphosis; Exclusion criteria: Patients having metabolic or hormonal disorders affecting the skeletal structure; patients receiving drugs with known affect on bone metabolism; patients currently receiving osteoporosis

treatment; patients not able to use brace;

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization will be performed using table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Postal code

Approval date

2001-10-27, 1380/08/05

Ethics committee reference number

386/الف

Health conditions studied

1

Description of health condition studied

Osteoporosis

ICD-10 code

M81.0

ICD-10 code description

Postmenopausal osteoporosis

2

Description of health condition studied

Kyphosis

ICD-10 code

M40.0

ICD-10 code description

Postural kyphosis

Primary outcomes

1

Description

Osteoporosis

Timepoint

At the start of the study and one year after the start of the intervention

Method of measurement

Bone mineral density

2

Description

Kyphosis

Timepoint

At the start of the study and one year after the start of the intervention

Method of measurement

Ruler

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Case group: A 600000 unit intramuscular vitamin D will be administered. A dose of 35 mg/ week oral Alendronate (Ostomeod, Modava Company, Iran) will also be administered as the osteoporosis drug of choice. Additionally, the case group will be intervened by the application of a Dynamic Hypercompression Brace containing one kilogram weight, and asked to use the brace 12 hours a day in their daily activities.

Category

Treatment - Devices

2

Description

Control group: A 600000 unit intramuscular vitamin D

will be administered. A dose of 35 mg/ week oral Alendronate (Ostomeod, Modava Company, Iran) will also be administered as the osteoporosis drug of choice.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bone and Joint Reconstruction Research center

Full name of responsible person

Alireza Mirzaei

Street address**City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr. Naserbakht

Street address

Iran University of Medical Sciences, Shahi Hemmat Highway,

City

Tehran

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Iran 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**

Bone & Joint Reconstruction Research Center

Full name of responsible person

Alireza Mirzaei

Position

Assistant Professor/ PhD

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Assistant professor/ PhD

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>