

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The immediate effects of thoracolumbar back brace, plastic body jacket, and trunk corset on the balance of older people with osteoprotic hyperkyphosis

Protocol summary

Study aim

To investigate the immediate effects of thoracolumbar back brace, plastic body jacket, and trunk corset on the balance of older people with osteoprotic hyperkyphosis

Design

A crossover study with a group of 20 participants who act as their own controls and receive one of three interventions and a control condition.

Settings and conduct

There is a convenience sampling method. participants will be recruited from the outpatient clinic of Alzahra hospital, Isfahan, Iran. The outcomes will be measured immediately after wearing each orthosis (intervention) and control condition (no orthosis).

Participants/Inclusion and exclusion criteria

Having an osteoprotic hyperkyphosis, age over 60 years, the history of two sudden falls in the last recent year, and cognitive ability to give informed consent

Intervention groups

The study interventions include: Intervention one: Spinomed orthosis Intervention two: plastic body jacket Intervention three: thoracolumbar flexible corset Control condition: no orthosis

Main outcome variables

Postural stability, balance and gait of participants are assessed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150210021034N7**

Registration date: **2020-03-27, 1399/01/08**

Registration timing: **retrospective**

Last update: **2020-03-27, 1399/01/08**

Update count: **0**

Registration date

2020-03-27, 1399/01/08

Registrant information

Name

Ebrahim Sadeghi-Demneh

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

2017-12-31, 1396/10/10

Actual recruitment end date

2018-09-11, 1397/06/20

Trial completion date

2018-09-21, 1397/06/30

Scientific title

The immediate effects of thoracolumbar back brace, plastic body jacket, and trunk corset on the balance of older people with osteoprotic hyperkyphosis

Public title

Orthotics in osteoprotic hyperkyphosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having an osteoporotic hyperkyphosis Age over 60 years
The history of two sudden falls in the last recent year
Cognitive ability to give informed consent

Exclusion criteria:

Severe visual or vestibular dysfunction History of fracture or surgery in the spine

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethical committee of Isfahan University of Medical Sciences, Isfahan, Iran

Street address

Hezar Jerib St.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-10-29, 1396/08/07

Ethics committee reference number

IR.MUI.REC.1396.3.523

Health conditions studied

1

Description of health condition studied

Osteoporotic hyperkyphosis

ICD-10 code

M40.15

ICD-10 code description

Other secondary kyphosis, thoracolumbar region

Primary outcomes

1

Description

Postural stability

Timepoint

Before intervention and right away after receiving intervention

Method of measurement

Participants are asked to stand quiet on the force-plate while put the feet together and keep the arms relaxed beside the body. The center of pressure is recorded during 60 second of standing.

2

Description

Timed get up and go

Timepoint

Before intervention and right away after receiving intervention

Method of measurement

Participants sit on a chair to start the test They are asked to walk with maximum speed during test. They rise with a "go" signal and walk until reach a line at 3 meters distance from the chair then turn and walk back to the chair and sit on it. The time is recorded using a stopwatch.

3

Description

Forward reach distance

Timepoint

Before intervention and right away after receiving intervention

Method of measurement

Participants stand with feet together and raise the arm at their shoulder level then leaning forward as much as could with heels in contact with the ground. The anterior displacement of the hand is measured using a yardstick or tape.

Secondary outcomes

empty

Intervention groups

1

Description

Spinomed-designed orthosis; This orthosis includes a semi-rigid structure on the back and shoulder straps which fit the orthosis on the body. The back structure is

formed on the spinal curve.

Category

Treatment - Devices

2

Description

Flexible thoracolumbar corset; This flexible corset has two posterior uprights to support the spine and anterior straps that fit the corset on the body.

Category

Treatment - Devices

3

Description

Plastic body jacket; This is a rigid bi-valved orthosis that fits on the body and supports the spine.

Category

Treatment - Devices

4

Description

Control group: No orthosis

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital, Isfahan, Iran

Full name of responsible person

Mohamad Saleki

Street address

Sofeh Blvd

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8174675731

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alzahra@mui.ac.ir

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http://alzahra.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahdi Nematbakhsh

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Ebrahim Sadeghi-Demneh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthopedics

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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

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The study data (excluding the personal details) can be shared with other researchers or systematic reviewers.

When the data will become available and for how long

No specific limitation is considered.

To whom data/document is available

No specific limitation is considered.

Under which criteria data/document could be used

No limit was set.

From where data/document is obtainable

People can send their request to the correspondence and obtain the data.

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

Request can be sent through an email.

Comments