

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The comparison of Spinomed and Elderly Spinal Orthosis on Kyphosis Angle, Back Pain and Quality of Life in Elderly with Thoracic Hyperkyphosis.

Protocol summary

Study aim

The comparison of Spinomed and Elderly Spinal Orthosis on Kyphosis Angle, Back Pain and Quality of Life in Elderly with Thoracic Hyperkyphosis.

Design

A randomized controlled clinical trial with parallel groups, single blind, randomized, Sample size is 60 elderly people over 60 years old.

Settings and conduct

The study population is among the elderly referred to Rasoul Akram Medical Center. Using envelopes the randomization process of the study variables is performed and for blinding, individuals from different groups will be referred on different days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Kyphosis angle above 50 degrees; Ability to sit and stand up and walk at least 10 meters independently; 60 years or older. Exclusion criteria: Physical abnormalities that are more important than kyphosis or impair the research process; People who had a history of fracture or surgery in the lower extremity or spine 12 months before the start of the study; Any illness or disorder that disables one's participation in sports and group activities.

Intervention groups

Intervention group 1: The first group received both Spinomed Orthosis and Back School exercise.
Intervention group 2: The second group received simultaneous spinal orthosis of aging and back school exercise. The people of each group come to Hazrat Rasoul Hospital on a specific day of the week until the end of treatment and under the supervision of a sports medicine specialist they perform their group exercises and their orthoses are adjusted by the relevant expert. Everyone is given their own workout schedule to continue their workouts at home during the week. The duration of wearing the orthosis is 2 hours a day. control

group: control group, will only do the back school exercise. Duration of exercise and method of exercise is similar to intervention group.

Main outcome variables

Angle of kyphosis; Quality of Life; pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140811018762N2**

Registration date: **2020-02-22, 1398/12/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-22, 1398/12/03**

Update count: **0**

Registration date

2020-02-22, 1398/12/03

Registrant information

Name

Mojtaba Kamyab

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of Spinomed and Elderly Spinal Orthosis on Kyphosis Angle, Back Pain and Quality of Life in Elderly with Thoracic Hyperkyphosis.

Public title
The comparison of Spinomed and Elderly Spinal Orthosis on Kyphosis Angle.

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Kyphosis angle above 50 degrees. Ability to sit and stand up and walk at least 10 meters independently. 60 years or older.
Exclusion criteria:
 Physical abnormalities that are more important than kyphosis or impair the research process. People who had a history of fracture or surgery in the lower extremity or spine 12 months before the start of the study. Any illness or disorder that disables one's participation in sports and group activities.

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
After the first visit to the clinic, individuals choose their treatment envelope from the available envelopes for each treatment group without knowing the groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
After the first visit to the clinic, individuals choose their treatment envelope from the available envelopes for each treatment group without knowing the groups. The groups receive their treatment separately.

Placebo
Not used

Assignment
Parallel

Other design features

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, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-08-31, 1398/06/09

Ethics committee reference number

IR.IUMS.REC.1398.494

Health conditions studied

1

Description of health condition studied

Thoracic hyperkyphosis

ICD-10 code

M40.04

ICD-10 code description

Postural kyphosis, thoracic region

Primary outcomes

1

Description

The kyphosis angle

Timepoint

At the beginning and end of the study (three months after the first evaluation).

Method of measurement

Inclinometer and radiograph

2

Description

Quality of Life

Timepoint

At the beginning and end of the study (three months after the first evaluation).

Method of measurement

SF36 questionnaire.

3

Description

Pain
Timepoint
At the beginning and end of the study (three months after the first evaluation).
Method of measurement
Visual Analogue Scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group received both Spinomed Orthosis and Back School exercise. The duration of use of orthosis and exercise is 3 months. The people of this group come to Hazrat Rasoul Hospital on a specific day of the week until the end of treatment and under the supervision of a sports medicine specialist they perform their group exercises and their orthoses are adjusted by the relevant expert. Everyone is given their own workout schedule to continue their workouts at home during the week. The duration of wearing the orthosis is 2 hours a day.

Category

Rehabilitation

2

Description

Intervention group: The second group received simultaneous elderly spinal orthosis and back school exercise. The duration of use of orthosis and exercise is 3 months. The people of this group come to Hazrat Rasoul Hospital on a specific day of the week until the end of treatment and under the supervision of a sports medicine specialist they perform their group exercises and their orthoses are adjusted by the relevant expert. Everyone is given their own workout schedule to continue their workouts at home during the week. The duration of wearing the orthosis is 2 hours a day.

Category

Rehabilitation

3

Description

Control group: The third group, which is the control group, will only do the back school exercise. Exercise time is 3 months. The control group is referred to Hazrat Rasoul Hospital on a specific day of the week until the end of treatment and under the supervision of a sports medicine specialist they perform group exercises. Everyone is given their own workout schedule to continue their workouts at home during the week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasoul Akram Hospital

Full name of responsible person

Dr. Mani Mahdavi

Street address

Second floor, Orthopedic Clinic, Hazrat Rasool Akram Hospital, Neyayeh Ave., Sattarkhan Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mojtaba Kamyab

Street address

School of Rehabilitation Sciences, Iran University of Medical Sciences, Shah Nazari St., Mirdamad Square, Iran

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Grant name

Grant code / Reference number

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

No

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr. Mojtaba Kamyab

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Dr. Mojtaba Kamyab

Position

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Latest degree

Ph.D.

Other areas of specialty/work

Others

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Zahra Rahimi

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The outcomes of this study will be interpreted into a manuscript and will be submitted to a peer reviewed journal

When the data will become available and for how long

Starting data access period 6 months after the article is published.

To whom data/document is available

Researchers working in academic centers who plan to use these findings in a systematic review and meta analysis.

Under which criteria data/document could be used

Due to the presence of the authors of this article in the academic center, there is a need for written permission from the university to submit data. Therefore, data will be sent no later than 6 months after applying for a written permission from the university.

From where data/document is obtainable

School of Rehabilitation Sciences, Iran University of

Medical Sciences, Dr Kamyab, Zahra Rahimi

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

Upon requesting the documentation, the researcher must obtain written approval from the university and

submit the documentation after obtaining permission. Therefore, with a time estimate of about 6 months after the request will be sent.

Comments