

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Studying the effect of Kyphologic and Maria Adelaide Orthoses on the Sagittal Spinal Curves in people with Scheuermann's Kyphosis: a randomized clinical trial

Protocol summary

Study aim

Studying the effect of Kyphologic and Maria Adelaide Orthoses on the Sagittal Spinal Curves in people with Scheuermann's Kyphosis

Design

The study is a randomized clinical trial with parallel groups (intervention and control). A total of 10 samples are selected based on previous studies. The samples are randomly divided into two equal groups using the kyphological orthosis and Maria Adelaide orthosis users.

Settings and conduct

Participating people are selected from among the clients to the Orthotics and Prosthetics Clinics of Isfahan and Yazd Universities of Medical Sciences and Royesh technical orthopedic clinic based on the entry and exit criteria. X-rays are taken of the patient's spine in a standing position. Both orthoses are custom-made. Molding, modification of the positive mold of orthosis is done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The kyphosis angle of the thoracic or thoracolumbar region should be more than 45 and less than 75 degrees! The Risser sign is between zero and two! The apex of the arch is at T7 or lower! There is no contraindication for using a brace. Exclusion criteria: Body mass index is more than 30! In addition to kyphosis, have scoliosis! Have musculoskeletal, neurological or metabolic diseases at the same time! Deformity of the spine is congenital. Have previously undergone spine surgery.

Intervention groups

The test group will receive the kyphologic orthosis and the control group will receive the Maria Adelaide orthosis.

Main outcome variables

Cervical Lordosis! Lumbar Lordosis! Thoracic Kyphosis! Cervical Sagittal Line! Sacral Inclination Angle! Pelvic Tilt

General information

Reason for update

corrections in Second recruitment center

Acronym

IRCT registration information

IRCT registration number: **IRCT20241013063348N1**

Registration date: **2024-12-04, 1403/09/14**

Registration timing: **prospective**

Last update: **2025-06-29, 1404/04/08**

Update count: **1**

Registration date

2024-12-04, 1403/09/14

Registrant information

Name

Mahmood Asayesh e Zarchi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3627 0341

Email address

toroyesh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-20, 1403/09/30

Expected recruitment end date

2025-12-21, 1404/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of Kyphologic and Maria Adelaide Orthoses on the Sagittal Spinal Curves in people with Scheuermann's Kyphosis: a randomized clinical trial

Public title

Studying the effect of Kyphologic and Maria Adelaide Orthoses on the Sagittal Spinal Curves

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The kyphosis angle of the thoracic or thoracolumbar region is more than 45 degrees Risser sign is between zero and two The apex of the arch is at T7 or lower There should be no prohibition to use an orthosis

Exclusion criteria:

The kyphosis angle of the thoracic region should be more than 75 degrees In addition to kyphosis, have scoliosis have musculoskeletal, neurological or metabolic diseases at the same time BMI is more than 30 Deformity of the spine is congenital Have a history of spine surgery

Age

From **8 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to control the confounding variables, the samples are randomly divided into two equal groups using the kyphological orthosis and the Maria Adelaide orthosis users. In random allocation, the size of each block is considered to be four people. The test group includes the users of kyphological orthosis and is marked with the letter N. The control group includes users of the Maria Adelaide orthosis and is marked with the letter O. Considering the two test and control groups, the number of 6 blocks is obtained. The arrangement of the members of each block will be (NNOO), (NOON), (NONO), (OONN), (ONNO) and (ONON). Then these 6 modes are written separately on the paper and poured into a container. With two draws, the number of four sample people for each group and eight people in total are selected. To choose the other two, we continue the lottery until one of the blocks (NOON), (NONO), (ONNO) or (ONON) comes out of the lottery.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Faculty of Nursing, Management and Rehabilitation - Isfahan University of Medica

Street address

Hezar jarib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2024-10-07, 1403/07/16

Ethics committee reference number

IR.MUI.NUREMA.REC.1403.112

Health conditions studied

1

Description of health condition studied

Scheuermann's Kyphosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Cervical Lordosis Angle

Timepoint

Before, one month and six months after the intervention

Method of measurement

EOS radiography device operator software

2

Description

Thoracic Kyphosis Angle

Timepoint

Before, one month and six months after the intervention

Method of measurement

EOS radiography device operator software

3

Description

Lumbar Lordosis Angle

Timepoint

Before, one month and six months after the intervention

Method of measurement

EOS radiography device operator software

4

Description

Sagittal Vertical Axis

Timepoint

Before, one month and six months after the intervention

Method of measurement

EOS radiography device operator software

5

Description

Sacral Inclination Angle

Timepoint

Before, one month and six months after the intervention

Method of measurement

EOS radiography device operator software

6

Description

Pelvic Tilt Angle

Timepoint

Before, one month and six months after the intervention

Method of measurement

EOS radiography device operator software

Secondary outcomes

1

Description

Satisfaction score

Timepoint

Six months after the intervention

Method of measurement

Questionnaire survey of orthosis and prosthesis users

Intervention groups

1

Description

Test group: Kyphologic Orthosis, It is a thermoplastic TLSO orthosis that extends anteriorly from the cavity of the Coracoid appendage to the symphysis pubis and posteriorly from the apex of the thoracic arch to the sacrum bone. This belt opens from the front and does not cover the areas of the gluteal muscles

Category

Treatment - Devices

2

Description

Control group: Adelaide Orthosis, A thermoplastic TLSO orthosis that has a pelvic girdle. This pelvic girdle extends anteriorly from the xiphoid process to the pubic region, and posteriorly, the posterior longitudinal pads

extend from the hip region to the thoracic kyphosis region. The pelvic belt opens from the back. In the anterior part of the brace, there is a sternal pad in the area below the supra sternal incision, and this pad is connected to the pelvic belt by two side metal bars.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthosis and Prosthesis Clinic, Faculty of Rehabilitation, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Ebrahim Sadeghi

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2

Recruitment center

Name of recruitment center

Shahid Sadoughi University of Medical Sciences clinics, and Royesh technical orthopedi institute

Full name of responsible person

Mahmoud Asayesh Zarchi

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Taleghani Blvd. Shahid daei 11 alley, deadend 11

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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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
Dr. Ebrahim Sadeghi
Position
Professor and faculty member of the Department of Orthosis and Prosthetics, Faculty of Rehabilitatio
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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

Yes - There is 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

Study information other than individual information is shared with other researchers.

When the data will become available and for how long

Information will be shared after results or data summaries are shared.

To whom data/document is available

Information is shared for academic purposes only.

Under which criteria data/document could be used

Information is shared for the research and teaching of applicants.

From where data/document is obtainable

People can get the information from the responsible person.

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

Applications must be sent via email.
(sadeghi@rehab.mui.ac.ir)

Comments