

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of immediate effect of designed brace on curve correction of adolescent idiopathic scoliosis

Protocol summary

Study aim

Evaluation of the immediate effect of designed thoracolumbosacral braces on curvature correction in patients with juvenile idiopathic scoliosis

Design

The study design will be performed as a clinical trial without control group, single group, non-blind, non-random, on 5 patients.

Settings and conduct

The study site is the radiology centers of Isfahan University of Medical Sciences. The immediate effect of curvature correction by a researcher-designed brace on patients is measured. In order to evaluate the immediate effect of orthosis, first a radiograph of the patient's spine (5 patients in a group) is taken in a standing position and the angle of curvature of the spine is determined by tapping method, then the patient wears the brace full time for one The moon is covered and the amount of recurrence is calculated after one month in the standing position on the frontal plate while the patient is wearing the brace.

Participants/Inclusion and exclusion criteria

The age range of participants is between 10 and 14 years; The racer mark of the participants is between 0 and 2; The initial curvature of the participants is between 25 and 45 degrees; the apex of the scoliotic curvature is below the fifth thoracic vertebra; Participants have not reached skeletal maturity or one year has passed since their maturity.

Intervention groups

Intervention group: Patients will wear braces full time (23 hours a day) for one month, and then the size of the curvature will be calculated before the intervention, and again after a month standing on the frontal plate while the patient wore the brace.

Main outcome variables

angle of curvature of the spine.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200516047459N6**

Registration date: **2022-01-09, 1400/10/19**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-09, 1400/10/19**

Update count: **0**

Registration date

2022-01-09, 1400/10/19

Registrant information

Name

Masoud Rafiaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5043

Email address

ma.rafiaei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-16, 1400/09/25

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of immediate effect of designed brace on curve correction of adolescent idiopathic scoliosis

Public title

The effect of spinal orthosis on spinal deviation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The age range of participants is between 10 and 14 years. Racer mark of participants should be between 0 and 2, The initial curvature of the participants should be between 25 and 45 degrees, The apex of the scoliosis curve is below the fifth thoracic vertebra;

Exclusion criteria:

Participants have reached skeletal maturity or more than one year has passed since their maturity.

Age

From **10 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **5**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

No.318 ,Rehabilitation college, Isfahan University and medical sciences, Hezar Jerib Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-11-13, 1400/08/22

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.181

Health conditions studied

1

Description of health condition studied

scoliosis

ICD-10 code

M41.115

ICD-10 code description

Juvenile idiopathic scoliosis, thoracolumbar region

Primary outcomes

1

Description

The size of the spine curvature that will be taken through the photograph by estimating the Cobb angle.

Timepoint

Before, Immediately after and one month after wearing the brace

Method of measurement

In order to evaluate the immediate effect of orthosis, a radiograph of the patient's spine is first taken standing and the angle of curvature of the spine is determined by a percussion method.

Secondary outcomes

1

Description

Angle of curvature of the spine

Timepoint

Before, immediately after and a month later

Method of measurement

Evaluate the angle of curvature using graphic photography

Intervention groups

1

Description

Intervention group (spine brace): In the first stage, the CT scan data of 5 people with scoliosis who have already had a CT scan at the request of a doctor and whose information is available in radiology centers, will be used for 3D modeling of the finite element, then design The optimal brace will be based on the 3D model made. After determining the optimal model of load application, this optimal model will be used in the second phase of the study in the treatment of braces of 5 people with juvenile idiopathic scoliosis. Then the patient wears the braces full time (23 hours a day) for one month and The amount of recurrence curve is calculated after one month of standing on the frontal plate while the patient is wearing a brace.

Category

Rehabilitation

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

Alzahra Hospital

Full name of responsible person

Masoud Rafiaei

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

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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

20

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

Masoud Rafiaei

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Documents and information about the participants are
confidential.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable