

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of two Cheneau brace made by two methods: "using a frame and 3D scanning" and "conventional" method on cobb angle correction, apical vertebral rotation, kyphosis and lordosis in adolescent girls with idiopathic scoliosis: a randomized clinical trial

Protocol summary

Study aim

Determining the effectiveness of two Cheneau orthoses made by the method of "use of a targeted frame and three-dimensional scanning" and the "usual" method in correcting Cobb angle, vertebra rotation, kyphosis and lordosis in adolescent girls with idiopathic scoliosis.

Design

The samples are randomly selected by block method.

Settings and conduct

CAD/CAM equipment is installed in the orthosis department of Farbod Technical Orthopedic Center and design and manufacturing work is done.

Participants/Inclusion and exclusion criteria

Adolescent idiopathic scoliosis patients are selected through accessible sampling. According to the entry and exit criteria, people from hospitals affiliated to Isfahan University of Medical Sciences are referred to the technical orthopedic clinic by a spine specialist. People who meet the entry criteria are included in the study after the approval of a specialist doctor. In order to simulate the two control and experimental groups, the coronal deformity angular ratio (C-DAR) is used, which is a measure to predict the long-term results of orthotic treatment. All people with double or single curvature with coronal deformity angular ratio below 6 can enter the study. People who do not use braces in any of the considered short-term and long-term courses and do not participate in the evaluations on time will be excluded from the study.

Intervention groups

In the intervention group, using a purposeful rotating frame, the primary forces of the brace are simulated and a 3D scan is taken from the patient's torso, without removing the problems of traditional methods. In the control group, a plaster mold is taken from the patient according to the principles of conventional molding, and

both the digital mold and the plaster mold go to the mold modification stage.

Main outcome variables

Cobb's angle, Apical vertebra rotation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231110060014N1**

Registration date: **2024-01-06, 1402/10/16**

Registration timing: **prospective**

Last update: **2024-01-06, 1402/10/16**

Update count: **0**

Registration date

2024-01-06, 1402/10/16

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of two Cheneanu brace made by two methods: "using a frame and 3D scanning" and "conventional" method on Cobb angle correction, apical vertebral rotation, kyphosis and lordosis in adolescent girls with idiopathic scoliosis: a randomized clinical trial

Public title
Effectiveness of two cheneau orthoses made by the CAD/CAM method and the conventional method in correcting idiopathic scoliosis in adolescent girls

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Risser sign between 0 and 2 Major curvature in the thoracolumbar or lumbar region The curvature between 20 and 45 degrees No history of surgery, trauma or fracture Do not be overweight Did not use braces or other treatment methods before entering the study Do not have heart or respiratory disease
Exclusion criteria:

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

Gender
Female

Phase
4

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyst

Sample size
Target sample size: **30**

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 block method, including the test (users of the new Cheneau brace) and the control (users of the usual Cheneau brace). The way of random assignment in both groups is that the size of each block is considered to be 4 people, and based on this and considering the two experimental groups that have new braces (N) and the control group that have regular braces (O), 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 states are written separately on paper and poured into a container, and with 8 rounds of lottery, the number of 15 sample people for each group and 30 people in total are selected.

Blinding (investigator's opinion)

Single blinded

Blinding description
In order to control biases, evaluation of values is done by two people, independently and separately. The evaluators include two experienced orthotists, apart from the researcher, who use the Digimizer software (Digimizer, MedCalc Software, V.5.7.5, Belgium) to draw and measure the case. They perform the need on the digital image of each patient. In fact, each evaluator does his work without knowing which treatment group each patient is assigned to. This software is used for anthropometric measurements. The radiographic image of each patient at each stage is analyzed three times by each evaluator and with a minimum interval of one week between repeated measurements, by both evaluators and randomly. Each evaluator will be unaware of the measurements made by another person as well as his previous evaluation of the same graph, and finally the average measurement of each evaluator will be recorded for each person. It should be noted that in order to match the measurement method of both evaluators as much as possible, before starting the evaluations, the reproducibility between the two evaluators is checked. In this way, ten numbers of radiographic images are given to each evaluator in a similar way, and if there is no significant difference between the numbers reported by the two evaluators, they start the measurements related to the study.

Placebo
Not used

Assignment
Parallel

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. 2, Khordad Str., Sattar Ave., Shariati Blvd., Najafabad City

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Postal code
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Approval date
2023-11-05, 1402/08/14

Ethics committee reference number
IR.MUI.NUREMA.REC.1402.134

Health conditions studied

1

Description of health condition studied

Scoliosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Cobb's angle: In general, the apex of any curve is the farthest vertebra from the central vertical sacral line with it. The top and bottom end beads in each curve define the boundaries of that particular curve. Cobb's angle is an index used to quantitatively evaluate the lateral deviation of the spine in the frontal plane and is usually known as the gold standard for diagnosing and evaluating the severity and predicting the progression of the deviation in scoliosis patients.

Timepoint

In both the control and experimental groups, each subject will have three radiological photographs in a standing position from two anterior-posterior and lateral views. Once before receiving the brace, when the brace is prescribed and the patient is prepared for casting or scanning. 20 days after the patient adapts to the orthosis, while the patient wears the brace, radiology imaging is done. The third imaging of the entire spine, without orthosis, is done for the long-term evaluation of the progress of the curve, with an interval of 6 months from the beginning.

Method of measurement

To measure the angle of the spine, the patient's spine should be taken with an anterior-posterior view while standing in a normal position.

2

Description

Apical vertebral rotation: Vertebral rotation takes place in the transverse plane. The amount of rotation of the vertebrae is of key importance in the prognosis of the disease and the effect of orthotic treatment or other interventions. The highest rotation is related to the vertex. Examining the rotation of the vertebral column around its longitudinal axis is an essential parameter in the study of adolescent idiopathic scoliosis.

Timepoint

In both the control and experimental groups, each subject will have three radiological photographs in a standing position from two anterior-posterior and lateral views. Once before receiving the brace, when the brace is prescribed and the patient is prepared for casting or scanning. 20 days after the patient adapts to the orthosis, while the patient wears the brace, radiology imaging is done. The third imaging of the entire spine, without orthosis, is done for the long-term evaluation of the progress of the curve, with an interval of 6 months

from the beginning.

Method of measurement

Apical vertebral rotation: To measure the amount of rotation of the vertebra, the Nash & Moe method is used, which has acceptable validity and reliability. In this method, five degrees are introduced for the rotation of the vertex.

Secondary outcomes

1

Description

Kyphosis and lordosis: Kyphosis and lordosis, respectively, refer to an anterior and posterior concavity of the spine in the sagittal plane, caused by the shape of the vertebral bodies and intervertebral discs.

Timepoint

Each subject will have three radiological photographs in standing position from two anterior-posterior and lateral views. Once before receiving the brace, when the brace is prescribed and the patient is prepared for casting or scanning. 20 days after the patient adapts to the orthosis, while the patient wears the brace, radiology imaging is done. The third imaging of the whole spine, without orthosis, is done for long-term evaluation of curve progress, with an interval of 6 months from the beginning.

Method of measurement

By measuring Cobb's angle, kyphosis and lordosis in teenagers, it is in the normal range between 20 to 40 and 35 to 60 degrees, respectively.

Intervention groups

1

Description

Intervention group: Cheneau Brace made using targeted framework and 3D scanning and design technology

Category

Rehabilitation

2

Description

Control group: Cheneau brace made in the conventional method

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Farbod Technical Orthopedic Clinic

Full name of responsible person

Davood farahmandi najafabadi

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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?
No
Title of funding source
Behsaz Teb Ajand Knowledge Base Company
Proportion provided by this source
67
Public or private sector
Private
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
Davood Farahmandi najafabadi
Position
Ph.D student

Latest degree
Master
Other areas of specialty/work
Orthosis & prosthesis
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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

Part of the data, such as the type and degree of deformity of the participants

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Only researchers working in university and scientific institutions

Under which criteria data/document could be used

Only judges

From where data/document is obtainable

To the project manager or researcher

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

It will be available to them without any problem

Comments

No problem