Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim
Determining the effectiveness of two Cheneaue 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

Name
Davood Farahmandi najafabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 4263 3389

Email address
d.farahmandi@rehab.mui.ac.ir

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 cheneaue orthoses made by the CADCAM 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 used 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 analyser

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

City

Najafabad

Province

Isfehan

Postal code

8513838413

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
Street address
Asgari build., Hoseinabad Ave., Vahid Blvd., Isfahan

sity
City
اصفهان
Province
Isfehan
Postal code
8175929919
Phone
+98 31 3620 2499
Email
D.farahmandi@rehab.mui.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Deputy Research and Technology
Street address
Ezarjarib Blvd., Isfahan city
City
اصفهان
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 3059
Email
vcr-office@med.mui.ac.ir
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
Street address
No.2, satar Ave.,shariati Ave.
City
Najafabad
Province
Isfehan
Postal code
8513838413
Phone
+98 31 4263 3389
Fax
Email
D.farahmandi@rehab.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
hossien asyaie mehr
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Orthosis & prosthesis
Street address
Hezarjarib Ave., Faculty of Rehabilitation, Isfahan city
City
Isfahan
Province
Isfehan
Postal code
817463461
Phone
+98 31 3792 5006
Email
asiyaeimehr@rehab.mui.ac.ir

Person responsible for updating data

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
Street address
No.2, satar Ave.,shariati Ave.
City
Najafabad

Province
Isfehan
Postal code
8513838413
Phone
+98 31 4263 3389
Fax
Email
D.farahmandi@rehab.mui.ac.ir

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