Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Designing and manufacturing a new brace, based on trunk asymmetry and pad pressure optimization and considering the efficacy on Cobb angle and trunk symmetry in adolescent idiopathic scoliosis

Protocol summary

Study aim

Designing and manufacturing a new brace, based on trunk asymmetry and pad pressure optimization and considering the efficacy on Cobb angle and trunk symmetry in adolescent idiopathic scoliosis

Design

volunteers will recruited in new brace and conventional brace groups. A pilot clinical trial , phase 2-3, single blind, parallel group. Sample size is 10 person, 5 subject in each group.

Settings and conduct

study will done in two major stage: first stage includes brace designing according to asymmetry of two half of body. second stage includes comparing brace efficacy in two groups. brace designing is done in four steps of creating best plane of symmetry, creating asymmetry map, rectifying the 3 dimensional trunk image and brace manufacturing using computer carving. In the second phase, subjects will compared in two groups of new brace and conventional brace. project will be done in a private clinic and faculty of rehabilitation of Iran university of medical sciences. patients are blinded of any difference in the brace mechanism.

Participants/Inclusion and exclusion criteria

Inclusion: Adolescents with idiopathic scoliosis higher than 25 degree who prescribed a spine brace At least 10 years old when prescribing a brace 0-2 risser sign when starting brace treatment Before menarche or less than one year after starting menarche in girls Non-inclusion: Musculo-skeletal disorder A history of treatment Perceptual disorder Skin disease Respiratory disorder

Intervention groups

Treatment group will receive new brace according to body asymmetry conventional brace group: will receive Boston or Milwaukee brace.

Main outcome variables

Cobb angle, trunk symmetry index, rib cage deformation, trunk deformity perception, treatment satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180918041062N1**
Registration date: **2019-02-27, 1397/12/08**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-27, 1397/12/08**
Update count: **0**

Registration date

2019-02-27, 1397/12/08

Registrant information

Name

shahrbanoo bidari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7124

Email address

bidarish.to12@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Designing and manufacturing a new brace, based on trunk asymmetry and pad pressure optimization and considering the efficacy on Cobb angle and trunk symmetry in adolescent idiopathic scoliosis

Public title
Designing and manufacturing a new brace, based on trunk asymmetry and considering the efficacy on spine lateral deformation and trunk symmetry in adolescent idiopathic scoliosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
adolescents with idiopathic scoliosis higher than 25 degree who prescribed a spinal brace. Age of at least 10 year old when brace prescription 0-2 risser sign when starting treatment Before menarche or less than one year after starting menarche in girls
Exclusion criteria:
Musculo-skeletal disorder A history of treatment Perceptual disorder Skin disease Respiratory disorder

Age
From **10 years** old to **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
All volunteers deliver a brace and are unknown of the difference in brace mechanism. they are not in the same place.

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
Madadkaran allay., Shahnazari st., Mohseni sq., Mirdamad blvd,

City
Tehran

Province
Tehran

Postal code
15459-13487

Approval date
2018-11-12, 1397/08/21

Ethics committee reference number
IR.IUMS.REC.1397.434

Health conditions studied

1

Description of health condition studied
Adolescent idiopathic scoliosis

ICD-10 code
M41.1

ICD-10 code description
Juvenile and adolescent idiopathic scoliosis

Primary outcomes

1

Description
Curve correction: Is described as the amount of curve reduction after brace wearing.

Timepoint
2.5 month after brace wearing

Method of measurement
Cobb method, radiography

Secondary outcomes

1

Description
Appearance symmetry index: Is a criteria to judge about the similarity and symmetry of two half of body

Timepoint
2.5 month after brace using

Method of measurement
Area symmetry index, Profile symmetry index

2

Description
Rib cage deformity: Is described as any deformation in rib cage, which occurs after scoliosis.

Timepoint
2.5 month after brace using

Method of measurement
Vertebro-costal angle, Lateral trunk shift, Thoracic ratio index, Rib index

3

Description
Trunk deformation perception: Is described as individual perception of trunk appearance regarding amount of symmetry.
Timepoint
2.5 month after brace using
Method of measurement
Trunk appearance perception scale

4

Description
Patient satisfaction: Patient satisfaction is a measure of the extent to which a patient is content with the health care which they received from their health care provider.
Timepoint
2.5 month after brace using
Method of measurement
Patient satisfaction questionnaire

Intervention groups

1

Description
Intervention group: in intervention group, new brace will be designed and manufactured based on trunk asymmetry, using 3 dimensional requisition. in this group, prominent area of one half of body than other half, is considered as the area of pad pressure applying. New brace includes unpredictable number of pads. number and trim line of pads is determined according the pattern of trunk asymmetry. pads are made from polypropylene 4 millimeter sheets. brace includes two anterior and posterior uprights. pads in posterior, are connected to posterior upright and in anterior, are connected to anterior upright by using hook and loop.
Category
Treatment - Devices

2

Description
Control group: conventional brace treatment group, don't change the routine treatment approach. in this group, brace is designed and manufactured according to routine protocol using manual casting method. In conventional protocol, brace can be a cervico-thoraco-lumbo-sacral(CTLSO) or thoraco-lumbo-sacral(TLSO). Conventional prescribed brace is a TLSO Boston or CTLSO Milwaukee brace.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran university of medical sciences
Full name of responsible person
Hassan Ghandehari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
Shahrbanoo Bidari

Position
Student
Latest degree
Master
Other areas of specialty/work
Orthopedics
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bidarish.to12@gmail.com

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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Participants data file (IPD): All data after being unrecognizable, will be published. Study protocol will be published clearly. Statistical analysis plan will be published Report of clinical study will be published completely.
When the data will become available and for how long
Starting time of accessibility to these information, would be after the end of study and publishing the result. It is expected this time would be at the start of 1399 (2020). Time duration of accessibility is unlimited.
To whom data/document is available
All people including researchers and clinicians can send a request for articles from this project. Only researchers who wants to do a meta analysis study, can send a request for documents.
Under which criteria data/document could be used
Researchers can use documents only in meta analysis studies, provided that cite the original article.
From where data/document is obtainable
Shahrbanoo Bidari tel: 00989399254668 Email: bidarish.to12@gmail.com Mojtaba Kamyab Email: mojtaba.kamyab@gmail.com
What processes are involved for a request to access data/document
Individual must send a request to mentioned email address. The request will be considered, if the person be eligible, documents will be sent.
Comments