

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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

shahrbanoobidari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2222 7124

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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

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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(CTL SO) or thoraco-lumbo-sacral(TLSO). Conventional prescribed brace is a TLSO Boston or CTL SO 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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Mojahedine eslam st., Shafa Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran 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

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

Shahrbano Bidari

Position

Student

Latest degree

Master

Other areas of specialty/work

Orthopedics

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

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Full name of responsible person

Mojtaba Kamyab

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Position

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Latest degree

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Other areas of specialty/work

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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

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

Shahrbano 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