

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of Schroth exercises and orthosis on patients with idiopathic scoliosis

Protocol summary

Study aim

The aim of this study was to evaluate the effect of Schroth exercises and orthosis on patients with idiopathic scoliosis.

Design

Double-blind randomized clinical trial with control group

Settings and conduct

First, the informed consent form will be signed by the subjects and one of their legal representatives. Then assigned to study groups (control, Schroth exercises and Orthosis) will be done. The Schroth exercise group trains for eight weeks, three sessions per week, one hour each session. The participants in orthosis group are also introduced to technical orthopedists. Depending on the results of the foot scan, the size of the foot length and the difference in the level of the trunk, a special orthosis is made for each person. Orthoses will be used for at least 4 hours a day for 8 weeks. The control group did not receive any intervention during this period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 12 to 16 years Having a Cobb angle greater than 10 degrees Having C-shaped idiopathic scoliosis Having no chronic diseases requiring any drug usage Having no other treatment which might affect scoliosis Exclusion criteria: Leg length discrepancy (greater than 5 mm) Having history of surgery in spine or lower leg Having history of regular exercise Presence of other neurological, muscular or rheumatic diseases

Intervention groups

Schroth Exercise Group Orthosis group

Main outcome variables

Cobb angle Pain Quality of life Perceived self-image Static balance Dynamic balance Foot pressure (static and dynamic)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200204046368N4**

Registration date: **2021-02-06, 1399/11/18**

Registration timing: **retrospective**

Last update: **2021-02-06, 1399/11/18**

Update count: **0**

Registration date

2021-02-06, 1399/11/18

Registrant information

Name

Zahra Raeisi

Name of organization / entity

Arak University

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3492

Email address

z_raisi13@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-08, 1399/10/19

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Schroth exercises and orthosis on patients with idiopathic scoliosis

Public title

Schroth exercises and orthosis in patients with scoliosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged 12 to 16 years Having a Cobb angle greater than 10 degrees Having C-shaped idiopathic scoliosis Having no chronic diseases requiring any drug usage having no other treatment which might affect scoliosis

Exclusion criteria:

Leg length discrepancy (greater than 5 mm) Having history of surgery in spine or lower leg Having history of regular exercise presence of other neurological, muscular or rheumatic diseases

Age

From **12 years** old to **16 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **39**

Randomization (investigator's opinion)

Randomized

Randomization description

The Randlist software is used to randomly assign subjects to intervention groups. At first, a code is assigned to each subject by this software. Then, they are randomly placed into three groups (n=13).

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will not be aware of the existence of other study groups. The data analyzer will not be aware of the groups classification. The information of the groups will be provided to the data analyzer in the form of numbers 1, 2 and 3 and for each participant with a code.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Arak University of Medical Sciences

Street address

Shahid Shiroodi Street

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2019-02-24, 1397/12/05

Ethics committee reference number

IR.ARAKMU.REC.1397.360

Health conditions studied**1****Description of health condition studied**

Scoliosis deformity

ICD-10 code

M41.11

ICD-10 code description

Juvenile idiopathic scoliosis

Primary outcomes**1****Description**

Cobb angle

Timepoint

Before and after the intervention

Method of measurement

Diers formetric 4d motion

2**Description**

Pain

Timepoint

Before and after the intervention

Method of measurement

Visual Analogue Scale

3**Description**

Quality of life

Timepoint

Before and after the intervention

Method of measurement

Scoliosis Research Society Outcomes Questionnaire (SRS-22)

4**Description**

Balance

Timepoint

Before and after the intervention

Method of measurement

Y balance test

5

Description

Foot pressure

Timepoint

Before and after the intervention

Method of measurement

Diers pedoscan

6

Description

Perceived self-image

Timepoint

Before and after the intervention

Method of measurement

Spinal Appearance Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The participants in the intervention group 1 perform schroth exercise for eight weeks, three sessions per week, and one hour per session.

Category

N/A

2

Description

Intervention group 2: Participants in the intervention group 2 used orthoses for eight weeks (at least four hours a day).

Category

N/A

3

Description

Control group: They will have the usual routine of their lives.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak university

Full name of responsible person

Zahra Raeisi

Street address

Shariati street

City

Arak

Province

Markazi

Postal code

3848177584

Phone

+98 86 3277 4031

Email

Z_raisi13@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak university

Full name of responsible person

Alireza Fazlali

Street address

Shariati street

City

Arak

Province

Markazi

Postal code

3848177584

Phone

+98 86 3262 2000

Email

d-research@araku.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak university

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

Arak University

Full name of responsible person

Zahra Raeisi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

Basij Square, Arak University

City

Arak

Province

Markazi

Postal code

3848177584

Phone

+98 86 3417 3492

Fax**Email**

Z_raisi13@yahoo.com

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

Arak University

Full name of responsible person

Zahra Raeisi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

Basij Square, Arak University

City

Arak

Province

Markazi

Postal code

3848177584

Phone

+98 86 3417 3492

Fax**Email**

Z_raisi13@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Arak University

Full name of responsible person

Zahra Raeisi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

Basij Square, Arak University

City

Arak

Province

Markazi

Postal code

3848177584

Phone

+98 86 3417 3492

Fax**Email**

Z_raisi13@yahoo.com

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

According to the approval of the ethics committee, we are not allowed to publish the information of the participants.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Some of the data will be available for use in scientific research.

When the data will become available and for how long

At least one year after the publication of the articles

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

If needed for review studies or use by academic researchers

From where data/document is obtainable

Responsible person for the study

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

Submit a request and then the corresponding author of study responds to the request.

Comments