Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 angel 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Alireza Fazlali
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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
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Zahra Raeisi
Position
Assistant professor
Latest degree
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Other areas of specialty/work
Sport Medicine

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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