

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of group exercising and adjusting the brace at shorter intervals on Cobb angle and Quality of life of patients with Idiopathic scoliosis

Protocol summary

Summary

Objectives and design: Bracing along with exercising is the most effective protocol in patients with idiopathic scoliosis which have Cobb angles of 25 to 45 degrees. However, since the psychological aspects of scoliosis treatment may affect the quality of life, and the exact time for adjusting the pads of Milwaukee brace is unknown; therefore the aim of this study was evaluating the effect of exercising in a group with adjusting the brace in shorter intervals, in compared with routine protocol, in the treatment of idiopathic scoliosis. Setting and conduct: Thirty-four patients with idiopathic scoliosis which had Cobb angles of 50 to 15 degrees will be included in this study and will be divided into experimental and control groups. The patients of two groups will participate in an eleven-week treatment program, with different between the two groups. Quality of life scores of both groups will be evaluated before and after intervention using SRS-22 questionnaire, as well as scoliosis angles before and after the intervention according to the primary and secondary radio graphic X-rays. participants: patients referring to the rehabilitation center of red crescent society with the Late onset idiopathic scoliosis diagnosis. Intervention: Group exercising and brace adjustment at shorter intervals. Main outcome measures variables: Cobb angle, and quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412094134N3**

Registration date: **2016-12-15, 1395/09/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-15, 1395/09/25

Registrant information

Name

Amir Ahmadi

Name of organization / entity

Rehabilitation collage of Iran university of medical science

Country

Iran (Islamic Republic of)

Phone

00982122227159 353 داخلی

Email address

amirahmadi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of group exercising and adjusting the brace at shorter intervals on Cobb angle and Quality of life of patients with Idiopathic scoliosis

Public title

Effect of group exercising and adjusting the brace at shorter intervals on Cobb angle and Quality of life of patients with Idiopathic scoliosis

Purpose

Treatment

Inclusion/Exclusion criteria
 The main Inclusion criteria: Late-onset idiopathic scoliosis; Milwaukee brace prescription; Trunk muscle strength grade 3 or higher; and no history of surgery on the spine; The main Exclusion criteria: no brace wearing for more than a week during the study; failure to follow the exercise program at home (i.e. exercise less than 6 hours per week); absenteeism in the practice session (related to the experimental group); and the absenteeism in the 3 months references (the control group)

Age
 From **8 years** old to **17 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **34**

Randomization (investigator's opinion)
 Not randomized

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rehabilitation college of Iran
 university of medical sciences

Street address

Tehran, Mirdamad Blv. , Mohseni Sq. , Shahnazari st. ,
 Nezaam alley, mailbox: 15875-4391

City

Tehran

Postal code

15459-13487

Approval date

2014-09-03, 1393/06/12

Ethics committee reference number

93/1825/320 /J

Health conditions studied

1

Description of health condition studied

Scoliosis

ICD-10 code

M41

ICD-10 code description

Scoliosis

Primary outcomes

1

Description

Cobb angle

Timepoint

Before intervention, three months after intervention

Method of measurement

Cobb method using Goniometer

2

Description

Quality of life

Timepoint

Before intervention, three months after intervention

Method of measurement

SRS-22 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: participants in this group, will doing exercise in a group of at least 3 members, under the supervision of a therapist skilled in the correction movements. This group exercise will be continued for 11 weeks, 2 days per week and each session was 2 hours. The Milwaukee brace of each patients will be adjusted by an experienced Orthotist, after the sessions. In the days between sessions, patients will required to exercise at home, alone for two hours daily.

Category

Other

2

Description

Control group: The exercises will be given to the patients in brochure format and they will asked to do these exercises 2 hours daily, without supervision of the therapist and also their braces will be adjusted every 3 months according to the scoliosis research society (as it is the common method of conservative management of scoliosis).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation center of red crescent society of Iran

Full name of responsible person

Zahra Hedayati

Street address

Tehran, Vanak sq. , Yasemi st, Red Crescent Society of Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran university of medical sciences

Full name of responsible person

Dr. Ali Javad Mousavi

Street address

Hemat Highway, Iran University of Medical Sciences, Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Iran university of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Amir Ahmadi

Position

Assistant Professor

Other areas of specialty/work**Street address**

Rehabilitation faculty, Mdad karan st., Shah nazari

AV, Mirdamad Blv., Madar Sq., Tehran

City

Tehran

Postal code**Phone**

+98 21 2222 8051

Fax**Email**

amirahmadi.pt@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Mojtaba Kamyab

Position

Assistant Professor

Other areas of specialty/work**Street address**

Rehabilitation faculty, Madad karan St., Shah Nazari Av., Madar Sq.,Mirdamad Blv., Tehran

City

Tehran

Postal code

1545913187

Phone

+98 21 2222 8051

Fax**Email**

mojtaba.kamyab@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Zahra Hedayati

Position

MSc Student

Other areas of specialty/work**Street address**

School of Rehabilitation, Nezam st., Shahnazari st., Madar Sq., Mirdamad Blv., Tehran

City

Tehran

Postal code

1545913187

Phone

+98 21882012415

Fax**Email**

zhr.hedayati@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty