

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of lumbosacral orthosis on pain, quality of life and spatiotemporal parameter of gait on elderly people with spondylolysis

Protocol summary

Study aim

The effect of lumbosacral orthosis on pain, quality of life and temporo-spatial parameters of walking in the elderly with spondylolysis

Design

Prospective interventional study: Sampling of 10 people with spondylolysis will be done. First, each person without orthosacral fills in the pain questionnaire while standing and the quality of life. In the third stage, after 2 months of using orthoses and following up patients with a weekly phone call on how to close and how long to wear braces, re-evaluate the patient and after re-completing the questionnaires, the experiment will be performed with lumbosacral orthosis.

Settings and conduct

In this study, we consider 10 people as a preliminary and finally the exact number of samples will be calculated according to the results for future studies. Sampling among people with spondylolysis who are members of centers affiliated to Isfahan University of Medical Sciences; it is going to happen. Eligible individuals are required to walk at a route of 13 meters in length and 3 meters in width at their chosen speed. Step by minute and step length and step time are measured.

Participants/Inclusion and exclusion criteria

Elderly 60 to 85 years; Spondylolysis in the 4th and 5th lumbar vertebrae; Have pain 4 days a week or more; Pain intensity should be at least 3 on the pain assessment scale; No history of drug use

Intervention groups

First, after completing the pain and quality of life questionnaire, each person first performs the test without orthosacral. Then we fit the orthosis on the patient's body and perform the tests again. Finally, after 2 months of using orthoses and following up patients by phone, the patient will be re-evaluated weekly.

Main outcome variables

Cadence; walking speed; stride length; pain; quality of

life; lumbosacral orthosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200516047459N5**

Registration date: **2022-01-02, 1400/10/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-02, 1400/10/12**

Update count: **0**

Registration date

2022-01-02, 1400/10/12

Registrant information

Name

Masoud Rafiaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5043

Email address

ma.rafiaei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-01, 1400/09/10

Expected recruitment end date

2022-12-01, 1401/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of lumbosacral orthosis on pain, quality of life and spatiotemporal parameter of gait on elderly people with spondylolysis

Public title
The effect of lumbar belt on pain and gait in adolescent with lumbar pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Elderly people aged 60 to 85 years who experience low back pain due to spondylolysis for at least 3 months
Spondylolysis in the 4th and 5th lumbar vertebrae Have pain 4 days a week or more Pain intensity at least 3 on the pain assessment scale No history of use Medication No sudden changes in pain
Exclusion criteria:
Spinal tumor Progressive neurological disorder Sensory disorders such as diabetes and neuropathy and .. Lumbar surgery in the last 3 years

Age
From **60 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

No.318, Research and Technology Development Building, Hezarjerib Street, Isfahan, Iran

City

Isfahan
Province
Isfahan
Postal code
8174673461
Approval date
2021-10-02, 1400/07/10
Ethics committee reference number
IR.MUI.NUREMA.REC.1400.129

Health conditions studied

1

Description of health condition studied

Spondylosis

ICD-10 code

M47

ICD-10 code description

Spondylosis

Primary outcomes

1

Description

Spatiotemporal parameter of gait on elderly people

Timepoint

Before, immediate and 2 months later

Method of measurement

Infrared cameras

Secondary outcomes

1

Description

Pain

Timepoint

Before, after and 2 months later

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

In the first stage, after completing the standing pain and quality of life questionnaire, each person first performs the test without orthoslombosacral. In the second step, we fit the orthosis on the patient's body and each person fills out the pain questionnaire while standing and performs the gait test with lumbosacral orthosis. In the third stage, after 2 months of using orthoses and following up patients with a weekly phone call on how to close and how long to wear braces, re-evaluate the patient and after re-completing the questionnaires, the experiment will be performed with lumbosacral orthosis.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Masoud Rafiaei

Street address

No 318, Rehabilitation college, Isfahan University of Medical Sciences, Hezarjerib Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5043

Email

ma.rafiaei@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash

Street address

Building No. 4, Vice Chancellor for Research and Technology, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

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

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Masoud Rafiaei

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Orthopedics

Street address

No. 318, Rehabilitation college

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5043

Email

ma.rafiaei@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Masoud Rafiaei

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Orthopedics

Street address

No318, Rehabilitation college

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5043

Email

ma.rafiaei@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Masoud Rafiaei

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Orthopedics

Street address

No. 318, Rehabilitation college

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5043

Email

ma.rafaei@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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The effect of lumbosacral orthosis on pain, quality of life and spatiotemporal parameter of gait on elderly people with spondylolysis

When the data will become available and for how long

6 month

To whom data/document is available

article authors

Under which criteria data/document could be used

Analysis and verification

From where data/document is obtainable

The main performer

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

send e-mail

Comments