

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Effect of Extensible and non-Extensible Lumbosacral Orthoses on the Flexion Relaxation Phenomenon in Patients with Chronic non-Specific Low Back Pain

Protocol summary

Study aim

Effect of Extensible and non-Extensible Lumbosacral Orthoses on the pain, disability, and Flexion Relaxation Phenomenon in Patients with Chronic non-Specific Low Back Pain

Design

The present study is a parallel-group, randomized clinical trial with the outcome assessor blinded. Patients with Chronic non-specific LBP will be randomly assigned to extensible or non-extensible lumbosacral orthosis groups.

Settings and conduct

All the assessments, interventions, and data collection steps will be carried out at the School of Rehabilitation Sciences, Shahid Beheshti University of Medical Sciences. The outcome assessor and statistician will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 65 yrs history of LBP for at least 12 weeks pain intensity of at least 3 on VAS a score of at least 12% on the ODI Standing and walking without assistance not receiving orthosis, kinesio-tape and or physical therapy for the last 3 months Exclusion criteria: having non-musculoskeletal LBP neurological symptoms due to nerve root compression severe spinal deformities history of spinal or abdominal surgery systemic diseases neuromuscular diseases BMI of more than 30 Antidepressive, Anxiolytic, Anticonvulsant drugs

Intervention groups

One group will be received an extensible lumbosacral orthosis and another group will be received a non-extensible lumbosacral orthosis. All patients will be asked to wear the LSO all day long for 4 weeks, except during rest and sleeping hours.

Main outcome variables

pain intensity on VAS Oswestry Disability Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200315046784N2**

Registration date: **2022-06-17, 1401/03/27**

Registration timing: **prospective**

Last update: **2022-06-17, 1401/03/27**

Update count: **0**

Registration date

2022-06-17, 1401/03/27

Registrant information

Name

Fatemeh Azadinia

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-19, 1401/03/29

Expected recruitment end date

2022-12-23, 1401/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Extensible and non-Extensible Lumbosacral Orthoses on the Flexion Relaxation Phenomenon in Patients with Chronic non-Specific Low Back Pain

Public title

Effect of lumbosacral orthosis on non-specific chronic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age 18 to 65 yrs history of LBP for at least 12 weeks pain intensity of at least 3 on VAS a score of at least 12% on the ODI Standing and walking without assistance not receiving orthosis, kinesio-tape and or physical therapy for the last 3 months

Exclusion criteria:

neurological symptoms due to nerve root compression severe spinal deformities history of spinal or abdominal surgery systemic diseases neuromuscular diseases BMI of more than 30 Antidepressive, Anxiolytic, Anticonvulsant drugs

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The group allocation will be performed through permuted block randomization at an assignment ratio of 1:1. For allocation concealment, the randomization codes will be kept in opaque, sealed, sequentially numbered envelopes. Sample size is estimated at 32, however, to take account of potential withdrawals, 40 patients (n=20 per group) will be recruited for the study. First, create and seal 20 treatment A envelopes and 20 treatment B envelopes. To create a block of 4, we will select 2 treatment A envelopes and 2 treatment B envelopes. We will shuffle these 4 envelopes thoroughly, and place this block of 4 in a separate pile. Then, we will prepare additional blocks of 4 until all 20 treatment A and B envelopes have been used. All additional blocks will be placed in their own individual piles. We will have 10 individual piles of shuffled blocks of 4, for example AAB, BBAA, ABBA, BAAB, ABAB, BABA.

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome assessor will be blinded to group allocation, because all dependent variables will be measured without the orthosis, and the patients will remove their orthosis before referring for post-intervention

assessment. Furthermore, all data will be encoded to prevent bias and to blind the statistician.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

the ethics committee of Iran University of Medical Sciences

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Shahid Hemmat Highway

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1449614535

Approval date

2021-06-29, 1400/04/08

Ethics committee reference number

IR.IUMS.REC.1400.299

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

non-specific chronic low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

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

disability score on Oswestry Disability Index

Timepoint

before and after 4 weeks intervention

Method of measurement

Oswestry Disability Index

2**Description**

pain intensity

Timepoint

before and after 4 weeks intervention

Method of measurement

Visual analogue scale

Secondary outcomes

1

Description

fear of movement (kinesiophobia)

Timepoint

before and after 4 weeks intervention

Method of measurement

Tampa Scale of Kinesiophobia

2

Description

back muscle endurance

Timepoint

before and after 4 weeks intervention

Method of measurement

Biering-Sørensen Test

3

Description

Flexion relaxation ratio

Timepoint

before and after 4 weeks intervention

Method of measurement

electromyography

Intervention groups

1

Description

Intervention group: Group A will be received an extensible lumbosacral orthosis. The patients will be asked to wear the orthosis all day long for 4 weeks..

Category

Treatment - Devices

2

Description

Intervention group: Group B will be received a non-extensible lumbosacral orthosis. The patients will be asked to wear the orthosis all day long for 4 weeks.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation Sciences, Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Fatemeh Azadinia

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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

Fatemeh Azadinia

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthotics and Prosthetics

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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

There is no plan for IPD publication.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Title and more details about the data/document

Our research findings will be shared with all researchers, and practitioners. We will publish our research findings in scientific journals.

When the data will become available and for how long

All documents can be shared 1 year after article publication

To whom data/document is available

Researchers and health practitioners

Under which criteria data/document could be used

Use of data is only possible by mentioning the name and organizational affiliation of the correspond and co-author of the project and the published article

From where data/document is obtainable

Fatemeh Azadinia

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

Send email to corresponding author.

Comments