

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Lumbosacral orthosis on the gait dynamics in chronic non-specific low back pain patients

Protocol summary

Study aim

Our aim is to determine any differences in the stride-to-stride fluctuations in low back pain patients while wearing lumbosacral orthoses ,i.e, CNS can perceive the passive stiffness provided by lumbosacral orthoses and make any motor control adaptations to this enhancement of spine stability.

Design

Twenty four (24) subjects with chronic non specific low back pain will participate in the study.This study is a parallel-group randomized controlled trial in which subjects will be randomly allocated to control and intervention groups.

Settings and conduct

The subjects walk on a level motorized treadmill using an eight-camera motion analysis. The data collection will do at first day of treatment and repeat at 3th week and 6th week after treatment. Subjects will be followed one month after the end of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patient with chronic non-specific low back pain and pain intensity from 1 to 6 that their pain lasts at least 6 months. Non inclusion criteria: Patients with specific low back pain and referral neurological pain to distal of lower limbs and patients who previously used lumbar support.

Intervention groups

The control subjects will receive physical therapy (exercises and electrotherapy) and intervention group will receive physical therapy as well as a semirigid LSO, 6-8 hour a day for 6 weeks.

Main outcome variables

Pain intensity; disability index; fear avoidance beliefs

General information

Reason for update

completion the information at the end of the study

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072828310N2**

Registration date: **2016-08-25, 1395/06/04**

Registration timing: **prospective**

Last update: **2020-01-08, 1398/10/18**

Update count: **1**

Registration date

2016-08-25, 1395/06/04

Registrant information

Name

Mohammad Ali Sanjari

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of Iran University of Medical Sciences

Expected recruitment start date

2015-10-22, 1394/07/30

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

2016-09-01, 1395/06/11

Actual recruitment end date

2017-06-30, 1396/04/09

Trial completion date

2017-06-30, 1396/04/09

Scientific title

Effect of Lumbosacral orthosis on the gait dynamics in

chronic non-specific low back pain patients

Public title

Effect of Lumbosacral orthosis on low back pain management

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Low back pain intensity from 1 to 6 Low back pain for at least 6 months 3 months from the last treatment session There should be acute exacerbation periods of low back pain Age between 18 to 50 years Subjects could be able to walk with preferred walking speed for 10 minutes so that pain is not barrier for walking

Exclusion criteria:

Specific low back pain such as disk herniation, fracture, spondylolisthesis Referral pain in the lower limbs History of spinal surgery History of trauma resulted in sprain, dislocation and fracture in spinal area Using drugs that interfere with walking Any previous use of lumbar supports gait imbalance and use of assistive devices

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **24**

Actual sample size reached: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed blindly by a permuted block randomization in which block sizes were randomly varied from two to four and allocation ratio was 1:1. An independent person performed the allocation via sealed, opaque envelopes numbered consequently to ensure the allocation concealment.

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessor and participants were blind to group assignment. While the data analysis was blindly conducted, due to the nature of the intervention (PT, LSO) in both groups, the blinding of the participants and outcome assessor during the test procedure was impossible and it didn't take place.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Hemmat highway

City

Tehran

Province

Tehran

Postal code

1545913487

Approval date

2015-05-25, 1394/03/04

Ethics committee reference number

IR.IUMS.REC.1394.3.41051230

Health conditions studied

1

Description of health condition studied

Chronic non-specific low back pain

ICD-10 code

M54.9

ICD-10 code description

Dorsalgia, unspecified , Backache NOS

Primary outcomes

1

Description

pain

Timepoint

before intervention, 3 weeks after intervention, 6 weeks after intervention, 1 month after the stop of intervention

Method of measurement

numerical pain rating scale

2

Description

disability

Timepoint

before intervention, 3 weeks after intervention, 6 weeks after intervention, 1 month after the stop of intervention

Method of measurement

Oswestry disability index questionnaire

3

Description

fear avoidance

Timepoint

before intervention, 3 weeks after intervention, 6 weeks after intervention, 1 month after the stop of intervention

Method of measurement

fear avoidance belief questionnaire

Secondary outcomes

1

Description

Fractal scaling index

Timepoint

before intervention, 3 weeks after intervention, 6 weeks after intervention, 1 month after the stop of the intervention

Method of measurement

motion analysis system, power law relationship between stride to stride fluctuations and time as measuring the slope of log/log-fluctuations plot

Intervention groups

1

Description

Intervention group will receive physical therapy (exercises and electrotherapy) as well as a semirigid lumbosacral orthosis for 6 weeks, 8 hour a day.

Category

Rehabilitation

2

Description

The control subjects will receive physical therapy (exercises and electrotherapy) for 6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation Sciences, Iran University of Medical Sciences

Full name of responsible person

Maryam Hekmatfard

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No. 17, Shahnazari St., Madar Sq., Mirdamad Blvd., School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology

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

Vice Chancellor for Research and Technology

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

School of Rehabilitation Sciences, Iran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sanjari

Position

Associate professor/ PhD in Biomechanics

Latest degree

Ph.D.

Other areas of specialty/work

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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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Individual Participant Data collected for the primary and secondary outcome measures will be shared after de-identification.

When the data will become available and for how long

If there is a request from researchers, the data will become available after paper publication.

To whom data/document is available

The data will be available for researchers working at the academic institutions.

Under which criteria data/document could be used

More analyses on the data should be performed under supervision of the researchers of this study.

From where data/document is obtainable

The data would be available through email: ma.hekmat@yahoo.com per requests received from academic researchers.

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

Whenever a request is received, first the researcher should be identified. Second, the aims of the study should be clarified. Further, all ethics related to recruitment of the subjects should be passed. The process will be clarified through email by details.

Comments