Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Mohammad Ali Sanjari

Name of organization / entity
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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
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Province
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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 aftter 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 aftter 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 aftter 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 aftre 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology
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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
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Position
Associate professor/ PhD in Biomechanics
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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