

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of lumbosacral support on postural control strategies and sensory integration in low back pain

Protocol summary

Summary

Objectives : The aim of this study is to assess the effect of lumbosacral support on postural control strategies and sensory integration in low back pain. Design: simple non-randomised control trial. Participants: In this study 30 young volunteer participate in each group (a group of chronic low back pain and a control group). Including major eligibility: low back pain patients had no other medical problem and at least 6 month pain history. The low back pain is non-specific type with unknown specific pathology. The pain intensity is less than 3/10 based on visual analog scale. Intervention: Different trials will be done in two main conditions: 1) with lumbosacral support 2) without lumbosacral support. Setting and conduct: Subjects stand on force plate barefoot , arms hanging on both sides in such a way that their heels distance is 10 cm. each subject does 4 trials and each trial lasting 75 second in both conditions, in order to Main outcome measures: center of pressure(COP) linear (anterior-posterior and lateral COP displacement ,COP mean velocity , COP area) and non-linear (entropy) analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020326346N1**

Registration date: **2016-05-23, 1395/03/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-23, 1395/03/03

Registrant information

Name

Gholamreza Olyaei

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University Of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-07-05, 1395/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lumbosacral support on postural control strategies and sensory integration in low back pain

Public title

Immediate effect of lumbosacral support on low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Including major eligibility: subjects with chronic low back pain! no history of another musculoskeletal disorder! no history of cardio - respiratory disorder! no history of surgery! non professional athlete Exclusion major eligibility: subject wouldn't be continue protocol! subject's disability in test! increase pain intensity or induced each comfort during test protocol! inappropriate

force plate's signal recording: hyperlordosis in lumbar

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ethic Committee Of Tehran University Of Medical Sciences

Street address

Pour Sina St, District 6, Tehran

City

Tehran

Postal code

Approval date

2016-03-05, 1394/12/15

Ethics committee reference number

IR.TUMS.REC.1394.2145

Health conditions studied

1

Description of health condition studied

Low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Low Back Pain

Primary outcomes

1

Description

anterior - posterior COP maximum displacement

Timepoint

befor wear lumbosacral support - during wear lumbosacral support

Method of measurement

force plate - milimeter

2

Description

lateral COP mmaximum displacement

Timepoint

befor wear lumbosacral support - during wear lumbosacral support

Method of measurement

force plate - milimeter

3

Description

mean COP velocity

Timepoint

befor wear lumbosacral support - during wear lumbosacral support

Method of measurement

force plate - mm/s

4

Description

COP area

Timepoint

befor wear lumbosacral support - during wear lumbosacral support

Method of measurement

force plate - mm²

5

Description

Approximate - Entropy

Timepoint

befor wear lumbosacral support - during wear lumbosacral support

Method of measurement

$ApEp(m,r,n)=\theta m-\theta m-1$

Secondary outcomes

1

Description

pain

Timepoint

befor and immediatly after test

Method of measurement

visual analog scale

Intervention groups

1

Description

wearing lumbosacral support in low back pain patient

Category

Treatment - Other

2

Description

wearing lumbosacral support in healthy control group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University Of Medical Sciences School Of Rehabilitation

Full name of responsible person

Masoud Ghofrani, PHD Candidate

Street address

School Of Rehabilitation, Piche Shemroon, Enghelab street, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Department of Tehran University of Medical Sciences

Full name of responsible person

Dr Masoud Yunesian

Street address

Tehran University of Medical Sciences, Ghods Street, Keshavarz Blv

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Department of Tehran 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

Tehran University of Medical Sciences, School Of Rehabilitation

Full name of responsible person

Dr Gholamreza Olyaei

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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