Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 mounth pain history. The low back pain is non-spesific 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

]ncluding major eligibility: subjects with chronic low back pain؛ no history of another muscoloskeletal 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 mnaximum 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)=Θm-Θm-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
City
Tehran

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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Person responsible for updating data

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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