

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of adding training on Biodex Balance system to stabilization exercise on pain and function of patients with low back pain from degenerative spondylolisthesis

Protocol summary

Summary

Aims: The aim of this randomized clinical trial is to compare the effect of stabilizing exercises performed with and without using Biodex Balance system on pain and functional disability of patients with low back pain of listethic origin. **Inclusion criteria:** 1. Patients with low back pain whose pain has been related to degenerative spondylolisthesis 2. Age between 30 and 70 3. BMI :18.5-30 4. No systemic disease 5. No history of fracture or surgery in low back 6. Not pregnant 7. Not having obvious mental and psychological problems 8. Have not received physiotherapy treatment during last 6 months **Exclusion criteria:** Patients' disagreement to continue treatment Using anti pain medicine during treatment Not complying with the home exercise program **Sample size:** there is no similar study. Using data in common field the sample in each group was estimated 15. **Interventions:** Patients in both groups will be visited in physiotherapy clinic every other day for 10 sessions. Both groups will receive conventional TENS (frequency 100 hz and pulse duration 100 micro second) for 25 minutes. All patients will receive strengthening, stretching and stabilizing exercises of abdominal and low back muscles in a pamphlet. Exercises will be taught and checked gradually during treatment sessions. Biodex group will receive 15 minute training on Biodex in addition to exercises, each session. The Biodex Balance System (BBS; Biodex Medical Systems, Shirley, NY), a balance device that has a movable balance platform providing up to 20° of surface tilt . The platform is interfaced with computer software (Biodex, version 3.1) that gives the amount of subject's balance using Overall stability index. Training on Biodex includes three ,5 minute training with 3 minutes rest in-between, with the Random training option . **Outcome measures:** Primary : Functional Rating Index questionnaire and VAS Secondary outcome measure : Overall postural stability index from Biodex

System All outcome measures will be measured at baseline , after 10 treatment sessions, after 2 months follow up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201511121139N2**

Registration date: **2017-01-01, 1395/10/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-01, 1395/10/12

Registrant information

Name

Safoora Ebadi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 912 175 7107

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2016-01-20, 1394/10/30

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding training on Biodex Balance system to stabilization exercise on pain and function of patients with low back pain from degenerative spondylolisthesis

Public title

The effect of Biodex Balance System on Degenerative Spondylolisthesis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1. Patients with low back pain whose pain has been related to degenerative spondylolisthesis; Age between 30 and 70; BMI :18.5-30;No history of fracture or surgery in the vertebral column; Not having obvious mental and psychological problems; Have not received physiotherapy treatment during last 6 months
Exclusion criteria: using anti pain medicine during treatment; If patient disagrees to continue treatment; patient not comply with exercise regimen at home

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization was done by using sealed envelopes.

Secondary Ids

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences ,Shahid Hemmat Highway .Tehran,1449614535,IRAN

City

Tehran

Postal code**Approval date**

2015-09-23, 1394/07/01

Ethics committee reference number

IR.IUMS.REC.1394 .260701

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

Degenerative Spondylolisthesis

ICD-10 code

M43.1

ICD-10 code description

Spondylolisthesis

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

Functional disability

Timepoint

Baseline, after 10 treatment sessions, after 2 months followup

Method of measurement

Functional Rating Index questionnaire

2**Description**

Pain

Timepoint

Baseline- after 10 treatment sessions- after 2 months followup

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Postural Stability Index

Timepoint

At baseline-After 10 sessions treatment- After 2 months followup

Method of measurement

Overall stability index given by Biodex software during postural test

Intervention groups

1

Description

Control group will receive conventional TENS (frequency 100 hz and pulse duration 100 micro second) for 30 minutes on the pain area in low back. In addition strengthening, stretching and stabilizing exercises of abdominal and low back muscles will be instructed and progressed during the treatment.

Category

Rehabilitation

2

Description

Intervention group will receive conventional TENS (frequency 100 hz and pulse duration 100 micro second) for 30 minutes on the pain area in low back. In addition strengthening, stretching and stabilizing exercises of abdominal and low back muscles will be instructed and progressed during the treatment in addition to 15 minutes training on the Biodex.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar Hospital

Full name of responsible person

Street address

Physical Medicine and Rehabilitation Department,
Firouzgar Hospital, Behafarin St., Karim khane zand
St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of
Medical Sciences

Full name of responsible person

Dr. Javad Ali Musavi

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Iran University of Medical Sciences, Shahid Hemmat
Highway, Tehran,1449614535,IRAN

City

Tehran

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, Iran 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

Iran University of Medical sciences, Faculty of
Medicine

Full name of responsible person

Dr. Safoora Ebadi

Position

Assistant professor, PhD PT

Other areas of specialty/work

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Assistant professor, PhD PT

Other areas of specialty/work

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Web page address
Person responsible for updating data
Contact
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