

# 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)

###### Phone

+98 912 175 7107

###### Email address

ebadi.s@iums.ac.ir

##### 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

##### Street address

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

#### Street address

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#### Web page address

## Person responsible for scientific inquiries

### Contact

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Iran University of Medical sciences, Faculty of Medicine

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Dr. Safoora Ebadi

#### Position

Assistant professor, PhD PT

#### Other areas of specialty/work

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#### Fax

#### Email

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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*