

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The comparison of flexi-bar and lumbar stability exercises on postural control of people with nonspecific low back pain

#### Protocol summary

##### Study aim

Changes in static stability indices, changes in dynamic stability, changes in pain, changes in isometric tolerance of dorsal muscles, changes in functional disability

##### Design

The trial included two intervention and control groups in which patients were randomly assigned to one group and only patients were kept blind to the type of treatment. The intervention group received Flexibar exercises and the control group received stabilizer exercises.

##### Settings and conduct

After enrollment of 30 patients with low back pain, the study was divided into intervention and control groups based on having inclusion criteria and no exclusion criteria. Initially, the variables of static and dynamic balance, functional disability, pain and isometric tolerance of the dorsal muscles of the two groups will be measured as "pre-assessment". Patients in the two groups will then be enrolled in a progressive exercise program for 10 sessions every other day, then repeat the same assessments as the "next assessment" one day after treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Body mass index of 20 to 25, local pain in the lumbar spine (between L1 and gluteal fold), chronic or recurrent pain for more than three months, pain intensity between 1 and 5 based on VAS scale. Exclusion criteria: Diabetic neuropathy, cardiovascular disease, respiratory, orthopedic, neurological and vestibular disorders, history of spine surgery, pregnancy, history of lumbar spine injection

##### Intervention groups

The intervention group received Flexibar exercises and the control group received stabilizer exercises.

##### Main outcome variables

Static and dynamic balance; Functional disability; Pain and isometric tolerance of the dorsal muscles

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191015045122N1**

Registration date: **2019-11-06, 1398/08/15**

Registration timing: **prospective**

Last update: **2019-11-06, 1398/08/15**

Update count: **0**

##### Registration date

2019-11-06, 1398/08/15

##### Registrant information

##### Name

Fatemeh Amiri doomari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3245 6119

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-22, 1398/09/01

##### Expected recruitment end date

2020-03-11, 1398/12/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison of flexi-bar and lumbar stability exercises on postural control of people with nonspecific low back pain

#### Public title

"The comparison of the effect of flexi-bar and lumbar stability exercises in treatment of low back pain"

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

All persons aged 20 to 45 years with chronic low back pain who have chronic or recurrent pain for more than three months Local pain in the lumbar spine (between l1 and gluteal fold) Pain severity between 1 and 5 based on VAS scale BMI 20 to 25

##### Exclusion criteria:

History of lumbar spine injection Pregnancy History of spine surgery Orthopedic, neurological, vestibular or cardiovascular, respiratory disorders Diabetic neuropathy

#### Age

From **20 years** old to **45 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **30**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Simple random method: Patients were given a number according to the order of their choice; then, with the help of a draw, the patients were divided into treatment and control groups. The first number was assigned to the treatment group and the next number entered the two groups, respectively.

#### 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

Ethics committee of Shahid Beheshti University of Medical Sciences

##### Street address

Third Floor, Faculty of Medicine, Next to Taleghani

Hospital, Evin, Shahid Chamran Highway, Tehran Town

#### City

Tehran

#### Province

Tehran

#### Postal code

1985717434

#### Approval date

2019-09-23, 1398/07/01

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1398.341

## Health conditions studied

### 1

#### Description of health condition studied

Nonspecific low backpain

#### ICD-10 code

M54.5

#### ICD-10 code description

Low back pain

## Primary outcomes

### 1

#### Description

Static posture control

#### Timepoint

Before the intervention and at the end of the intervention

#### Method of measurement

Bertec Force plate machine

### 2

#### Description

Dynamic posture control

#### Timepoint

Before the intervention and at the end of the intervention

#### Method of measurement

Star Excursion Balance Test

## Secondary outcomes

### 1

#### Description

Severity of pain

#### Timepoint

Before the intervention and after the intervention

#### Method of measurement

Visual analogue scale (VAS)

### 2

#### Description

Functional disability

#### Timepoint

Before the intervention and after the intervention  
**Method of measurement**  
Oswestry questionnaire

### 3

**Description**  
Isometric Tolerance of the Dorsal Muscle  
**Timepoint**  
Before the intervention and after the intervention  
**Method of measurement**  
Sorensen Test

## Intervention groups

### 1

**Description**  
Intervention group: This group receives 20 minutes of routine physiotherapy treatment including TENS, Hot pack, US, each session, followed by 15 minutes of bike warm-up and stretching exercises including cuff, hamstring, iliopsoas and back muscles, followed by 30 minutes Flexi-Bar exercises (Flexi-Bar of an elastic rod about 7.0 mm in diameter and 5.1 meters long with two ends fluctuating. Shaking flexi-load produces vibrational excitation at a low frequency of 5 HZ). They do it progressively. These exercises include shaking the bar on the horizontal, sagittal, and frontal plates. At the end, they do stretching exercises, such as stretching the cuff muscles, hamstring, iliopsoas, and back muscles for cool down.  
**Category**  
Rehabilitation

### 2

**Description**  
Control group: This group receives 20 minutes of routine physiotherapy treatment including TENS, Hot pack, US, each session, followed by 15 minutes of bike warm-up and stretching exercises including cuff, hamstring, iliopsoas and back muscles, followed by 30 minutes stability exercises including abdominal drawing-in, bridging, bird-dog exercise, Supine Dead Bugs progressively, 10 to 20 repetitions of each exercise. At the end, they do stretching exercises, such as stretching the cuff muscles, hamstring, iliopsoas, and back muscles for cool down.  
**Category**  
Rehabilitation

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Physiotherapy clinic in Shahid Beheshti Rehabilitation School  
**Full name of responsible person**  
Fatemeh Amiri Doomari

**Street address**  
No 11, Shahid Beheshti Ave. Azadi Square, Kerman Town  
**City**  
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**Postal code**  
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+98 34 3245 6119  
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fatemehamiri4727@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Dr. Afshin Zarqi  
**Street address**  
Vice chancellor for research and technology, floor 5, Headquarters Building 2, Shahid Beheshti University of Medical Sciences and Health Services, Next to Taleghani Hospital, Shahid Abbas Arabi Street (Parvaneh), Yemen Street, Shahid Chamran Highway, Tehran Town  
**City**  
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**Province**  
Tehran  
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1985717434  
**Phone**  
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**Email**  
zarghi@smbu.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shahid Beheshti University of Medical Sciences  
**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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Fatemeh Amiri doomari

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Mohammad Mohsen Roostayi

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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**Fax****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available