

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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+98 34 3245 6119

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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

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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

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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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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