

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of 16 sessions core stabilization exercises on spine kinematics during walking both with and without load in patients with non-specific chronic low back pain and comparison with healthy control group

Protocol summary

Study aim

The aim of this study is to evaluate the effect of spinal stabilization exercises on the spine kinematics during walking.

Design

A concealed, controlled clinical trial with a parallel group design of 30 patients healthy

Settings and conduct

Patients with a history of at least 3 months Non-specific chronic Low Back Pain (NCLBP) in the range of 18-45 years will enrolled after filling out a consent form. Each patient will complete the perceived pain questionnaire and the Oswestry Disability Questionnaire. Then in the first session, the spine kinematics will be evaluated in the motion analysis laboratory. Markers are placed on the trunk (acromion process and T12), lumbar (T12, L3 and S2), pelvis (bilateral ASIS and PSIS) and foot (bilateral posterior heel center and fifth MTP) and the patient is asked to walk with self-selected daily speed in a direction of 10 meters at a rate of 3 times without load and 3 times with a load approximately 10% of their body weight. Then, each patient participate in the 16 sessions of patient-specific spinal stabilization exercise training that will be given three times a week for 6 weeks. In the final session, pain, disability and spinal column kinematic will be assessed.

Participants/Inclusion and exclusion criteria

Inclusion: Low back pain from lower thoracic rib to the upper gluteal fold lasted more than 12 weeks. The range of pain would between 3-6 according to the VAS
Exclusion: acute low back pain, any illness and disorders in other limbs, gait disturbance, Any medical condition who have contraindications to exercise therapy.

Intervention groups

16 sessions of patient-specific spinal stabilization exercise training in patients group, no intervention will be made in the control group.

Main outcome variables

pain, disability and kinematic parameters of the spine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080829264N1**

Registration date: **2016-08-28, 1395/06/07**

Registration timing: **prospective**

Last update: **2019-05-12, 1398/02/22**

Update count: **1**

Registration date

2016-08-28, 1395/06/07

Registrant information

Name

Rasool Bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3344 1022

Email address

rasool.bagheri@ymail.com

Recruitment status

Recruitment complete

Funding source

IRAN University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-04-19, 1396/01/30

Actual recruitment start date

2016-10-18, 1395/07/27

Actual recruitment end date

2017-04-08, 1396/01/19

Trial completion date

2017-06-10, 1396/03/20

Scientific title

The effect of 16 sessions core stabilization exercises on spine kinematics during walking both with and without load in patients with non-specific chronic low back pain and comparison with healthy control group

Public title

The effects of spinal specific exercise therapy for treatment of chronic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Low back pain from lower thoracic rib to the upper gluteal fold low back pain which lasted more than 12 weeks The range of pain would between 3-6 according to the VAS

Exclusion criteria:

Any medical condition who have contraindications to exercise therapy. Acute low back pain or back pain that occurred in less than 12 weeks. BMI above 25 kg/m². Sciatic nerve root involvement. Pain radiating to the leg below the knee. Feeling paresthesia in the legs. Motor deficits in the lower limb muscles (MMT, grade 3.5 and less on the basis of Kendall approach). Acute spinal disc herniation (MRI reports or medical reports). History of surgery and lumbar spine fractures or other spinal structures (self-reported). Malignancy(self-reported). Pregnancy(self-reported). Radicular symptoms during daily activities, especially walking (self-reported). During the intervention, the patient will be banned from any sports activities.

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

N/A

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**

Ethics committee of IRAN University of Medical Science

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"Next to the Milad Hospital" "Hemmat Highway"

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Tehran

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Tehran

Postal code

3513138111

Approval date

2016-07-31, 1395/05/10

Ethics committee reference number

IR.IUMS.REC 1395.9211342205

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

chronic low back pain

ICD-10 code

M54.5

ICD-10 code description

Loin pain, Low back strain

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

spinal kinematic

Timepoint

before and after treatment

Method of measurement

motion analysis system of qualysis

2**Description**

disability

Timepoint

before and after treatment

Method of measurement

ODI disability quasionnare

3**Description**

pain

Timepoint

before and after treatment

Method of measurement

100 mm VAS scale

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

pain due to the core stabilization exercise

Timepoint

during assessment and treatment

Method of measurement

self reported

Intervention groups**1****Description**

specific spinal stabilization exercise that lasted in 16 sessions and 6 weeks and 3 times in each week. each session lasted for 45 minutes.

Category

Rehabilitation

2**Description**

In control healthy subjects, There will be no intervention.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

School of Rehabilitation

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Ismail Ebrahimi Takamjani

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Ismail Ebrahimi Takamjani

Position

Ph.D of Physiotherapy

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

No - There is not 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

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Rasool Bagheri

Position

Ph.D