

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The investigation on the effect of lumbar stabilization exercises on the size of multifidus muscles and balance index in patients with chronic low back pain

Protocol summary

Summary

Objective: It has been shown that the size of multifidus muscle reduces in the patients with chronic low back pain (CLBP). As these muscles are responsible to provide the sensory information which is necessary for balance control system, we have supposed the multifidus atrophy may damage balance control system and consequently may provide poor posture for CLBP patient and delay healing process for them. Therefore, we have design this study to investigate the relationship between the size of lumbar multifidus muscle and balance control pattern in CLBP patients and also to find if lumbar stabilizing exercises may increase the size of multifidus muscle and improve its sensory output for balance control system in CLBP patients. Method: By considering Inclusion Criteria (Patient who suffer chronic low back pain for more than 3 months, without any certain reason) and Exclusion criteria (Neuromuscular, Musculoskeletal, Cardiovascular, respiratory and diabetic conditions, Systemic disease, Spondylolistesis or spondylolysis, surgical procedure on lumbar, pressure on the lumbar nerve root, disc herniation, Polyneuropathy, Carsinoma, lumbar trauma report within tha last week,vertebral tumor, pregnancy and low back patients who received lumbar exercise within the last three months). 60 CLBP patients will be randomly assigned in one of the two experimental groups (Stabilization Exercise group and Mc-Kenzi Exercise group, n=30 in each group). The protocol include twice daily exercise for period of 4 weeks. All measurements include; the level of pain, size of lumbar multifidus, static and dynamic balance and functional performance.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810161254N4**

Registration date: **2010-04-24, 1389/02/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-04-24, 1389/02/04

Registrant information

Name

Amir Hoshang Bakhtiary Davijani

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 1444 1983

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2010-03-01, 1388/12/10

Expected recruitment end date

2010-10-01, 1389/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The investigation on the effect of lumbar stabilization

exercises on the size of multifidus muscles and balance index in patients with chronic low back pain

2/16857/ĭ

Public title

The investigation on the effect of lumbar stabilization exercises on the size of multifidus muscles and balance index in patients with chronic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patient who suffer chronic low back pain for more than 3 months, without any certain reason.
Exclusion Criteria: Neuromuscular, Musculoskeletal, Cardiovascular, respiratory and diabetic conditions, Systemic disease, Spondylolistesis or spondylolysis, surgical procedure on lumbar, pressure on the lumbar nerve root, disc herniation, Polyneuropathy, Carcinoma, lumbar trauma report within the last week, vertebral tumor, pregnancy and low back patients who received lumbar exercise within the last three months

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **33**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Semnan University of Medical Sciences

Street address

Basij Blv. Research and Educational Affair

City

Semnan

Postal code

Approval date

empty

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Chronic Low Back Pain

ICD-10 code

S30-S39

ICD-10 code description

Injuries to the abdomen, lower back, lumbar spine and pelvis

Primary outcomes

1

Description

Index of static and dynamic balance

Timepoint

Before and after 6 week lumbar stabilization exercise and 3 months follow up

Method of measurement

Biodex Balance System

2

Description

Size of Lumbar Multifidus Muscles

Timepoint

Before and after 6 week lumbar stabilization exercise and 3 months follow up

Method of measurement

Honda Sonography system

3

Description

Low Back Pain

Timepoint

Before and after 6 week lumbar stabilization exercise and 3 months follow up

Method of measurement

Visual Analogue Scale

4

Description

Update 2011.02.26 : Lumbar lordosis angle

Timepoint

Update 2011.02.26 : before and after 6 weeks lumbar stabilization exercise and after 3 month follow-up

Method of measurement

Update 2011.02.26 : Using flexible ruler

Secondary outcomes

empty

Intervention groups

1

Description

Lumbar Stabilization Exercises (Experimental Group), 15 min, twice daily, for Six week

Category

Rehabilitation

2

Description

Lumbar Mc-Kenzi Exercises (Control group for ethical consideration to provide treatment for patients), 15 min, twice daily for 6 weeks

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Musculoskeletal Rehabilitation Research Center

Full name of responsible person

Street address

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Eductaion of Semnan University of Medical Sciences

Full name of responsible person

Dr Mohammad Fanoush

Street address

Basij Blv, Semnan University of Medical Sciences

City

Semnan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research and Eductaion of Semnan 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

Rehabilitation Faculty, Semnan University of Medical Sciences

Full name of responsible person

Amir Houshang Bakhtiary

Position

PhD In Physiotherapy/ Associate Professor

Other areas of specialty/work

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Full name of responsible person

Amir Houshang Bakhtiary

Position

PhD/ Associat Professor

Other areas of specialty/work

Street address

City

Semnan

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Phone

Fax

Email

Web page address

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