

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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, Spondylolisthesis 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). 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

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Name of organization / entity

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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/ĩ
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	Health conditions studied
Purpose Treatment	1
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, Carsinoma, lumbar trauma report within tha last week, vertebral tumor, pregnancy and low back patients who received lumbar exercise within the last three months	Description of health condition studied Chronic Low Back Pain
Age From 18 years old to 65 years old	ICD-10 code S30-S39
Gender Female	ICD-10 code description Injuries to the abdomen, lower back, lumbar spine and pelvis
Phase N/A	Primary outcomes
Groups that have been masked No information	1
Sample size Target sample size: 33	Description Index of static and dynamic balance
Randomization (investigator's opinion) Randomized	Timepoint Before and after 6 week lumbar stabilization exercise and 3 months follow up
Randomization description	Method of measurement Biodex Balance System
Blinding (investigator's opinion) Single blinded	2
Blinding description	Description Size of Lumbar Multifidus Meuscles
Placebo Not used	Timepoint Before and after 6 week lumbar stabilization exercise and 3 months follow up
Assignment Parallel	Method of measurement Honda Sonography system
Other design features	3
Secondary Ids empty	Description Low Back Pain
Ethics committees	Timepoint Before and after 6 week lumbar stabilization exercise and 3 months follow up
1	Method of measurement Visual Analogue Scale
Ethics committee	4
Name of ethics committee Ethics Committee of Semnan University of Medical Sciences	Description Update 2011.02.26 : Lumbar lordosis angle
Street address Basij Blv. Research and Educational Affair	Timepoint Update 2011.02.26 : before and after 6 weeks lumbar stabilization exercise and after 3 month follow-up
City Semnan	Method of measurement Update 2011.02.26 : Using flexible ruller
Postal code	Secondary outcomes empty
Approval date empty	
Ethics committee reference number	

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 Education 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 Education 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

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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