Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, Musculosketal, 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

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Name of organization / entity

Semnan University of Medical Sciences

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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

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, Musculosketal, 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
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
2/16857/Ĩ

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 Meuscles
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 ruller

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
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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