

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

comparison between effects of core stabilization and Mckenzie exercises in mechanical low back pain

Protocol summary

Study aim

this study will compare effects of Mckenzie exercises and core stability exercises in pain based on VAS scale, range of motion of flexion in standing based on FTF, disability based on ODI questionnaire and their function based on unilateral single limb stance

Design

randomized clinical parallel group trial with double blinded via dice on 44 patients will be done and even dedicating to Mckenzie exercises group and odd dedicating to core stability exercises group

Settings and conduct

this study conducts in non invasive low back pain treatment field with exercise therapy. blinding occurs with giving each participant a code and not naming exercises for patients. Range of motion will be measured with a ruler measuring tip of fingers to floor in flexion in standing position also ODI questionnaire will be used for disability, VAS for pain and unilateral single limb stance for function

Participants/Inclusion and exclusion criteria

patients with mechanical low back pain with or without radiculopathy which does not have red flags and not have any surgeries in Lumbar vertebrae region and also have age between 30 to 70 with BMI lower than 30 will be eligible to participate in this study

Intervention groups

in Mckenzie exercises group according to assessment done, one of these three exercises will be prescribed and progressed respectively if the patients did not get worse: prone lying, prone lying on elbow, extension in lying. In core stability exercises after mechanical assessment done three types of exercises will be prescribed: bridging, unilateral prone leg extension, abdominal drawing in

Main outcome variables

changes in pain of patients; changes in range of motion; changes in function; changes in disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230806059059N1**

Registration date: **2023-08-23, 1402/06/01**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-23, 1402/06/01**

Update count: **0**

Registration date

2023-08-23, 1402/06/01

Registrant information

Name

Hamidreza Nemati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3448 0756

Email address

hmdreza9898@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-16, 1402/05/25

Expected recruitment end date

2023-09-15, 1402/06/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison between effects of core stabilization and Mckenzie exercises in mechanical low back pain

Public title

exercise therapy in lowback pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Lowback pain with or without radiculopathy Having a defined baseline for painful positions Having at least pain level of 2 based on VAS BMI lower than 30

Exclusion criteria:

history of any surgeries in Lumbar vertebrae including laminectomy or etc History of tumor or possibility of it History of trauma or possibility of infection or fracture Unwillingness to continue at any stages Urinary or fecal incontinence Pregnancy Hamstring shortness brain injuries Vestibular disorders, alcohol or drug abuse and psychotropic drugs

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

participants will fill their demographic and personal data. Their pain based on VAS, range of motion based on FTF, disability based on ODI questionnaire and functional status based on unilateral single limb stance will be measured. All participants will be assessed via mechanical assessment form (mechanical diagnosis and therapy from Mckenzie institute) and then we will use a dice, even puts them in Mckenzie exercises group and odd puts them in core stability exercises group

Blinding (investigator's opinion)

Double blinded

Blinding description

all procedures except name of groups will be described to patients so that they will perform exercises according to the educations without knowing their group name. Each participants will be paired by a code to their names in a separate paper from their files so the final assessor would be blind of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

in this study we do not use any type of modalities or drugs and all participants will only do the prescribed exercises at the time of study Furthermore; all of them will be assessed via mechanical assessment form

introduced by Mckenzie institute before grouping

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of shahid beheshti university of medical sciences

Street address

No 16, Arghavan street, west mahan Blvd

City

Karaj

Province

Alborz

Postal code

3145944516

Approval date

2023-05-30, 1402/03/09

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.093

Health conditions studied

1

Description of health condition studied

Mechanical low back pain

ICD-10 code

M54.5

ICD-10 code description

Low Back Pain

Primary outcomes

1

Description

flexion in standing range of motion

Timepoint

before study and after 8 sessions therapy

Method of measurement

ruler

2

Description

pain intensity

Timepoint

before study and after 8 sessions therapy

Method of measurement

visual analogous scale

3

Description

disability

Timepoint

before study and after 8 sessions of therapy

Method of measurement

oswetry disability index

4**Description**

function and balance

Timepoint

before study and after 8 session therapy

Method of measurement

using a striated curtain with 1 meters away from patient. Test if positive if any compensatory movement or deviation occurs that does not turn back to the starting position immediately

Secondary outcomes

empty

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

Intervention group: core stability group in this group patients after mechanical assessment with mechanical assessment form will be educated to perform abdominal drawing in, unilateral prone leg extension and bridging in two sets and each set 5 seconds holding contraction and 5 minutes rest between each set.

Category

Treatment - Other

2**Description**

Intervention group: Mckenzie exercises in this group after assessment with mechanical assessment form patients will first do prone lying for 5 minutes, if symptoms does not get worse they will be progressed to prone on elbow position for 5 minutes. again if symptoms does not get worse they will perform extension in lying to end range and hold it for 2 seconds and 10 repetition then they will rest for 5 minutes and repeat for 10 times.

Category

Treatment - Other

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

Iranmehr physiotherapy clinic

Full name of responsible person

Mehdi Nikzad

Street address

Rose dead end, Eram Blvd, Mehrshahr

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hoda Niknam

Street address

Damavand st, Emam ali Exp. way

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1616913111

Phone

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Email

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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

Hamidreza Nemati

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data related to pain,disability,range of motion,balance and function can be reported.Other data including demographic features can also be reported but they are not the purpose of this study

When the data will become available and for how long

start of publishing data:3 months after conclusions reported

To whom data/document is available

All of physiotherapist are allowed

Under which criteria data/document could be used

for the data mentioned above, no other permissions are required and all of physiotherapist are allowed to use these data.

From where data/document is obtainable

Just email of Hamidreza Nemati,Conductor of study is available Hmdrea9898@gmail.com

What processes are involved for a request to access data/document

The detail of data asked should be emailed in one mail and after about one to two weeks the data will be send for them

Comments