Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 on motion of flexion in standing based on FTF,disability based on ODI questionnaire and their function based on unilateral single limb stnace

Design
randomized clinical parallel group trial with double blinded via dice on 44 patients will be done and even dedicates to Mckenzie exercises group and odd dedicates 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 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 type 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)
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+98 26 3448 0756
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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 assesment 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 committe 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 net 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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3186656825
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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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Tehran
Province
Tehran
Postal code
1616913111
Phone
+98 21 7754 2057
Email
info@sbmu.ac.ir
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

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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