Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Examining the amount of pain and muscle atrophy visible in MRA of patients with non-specific chronic back pain before and after exercise therapy and corrective exercises in Imam Khomeini Hospital, Sari from 2022 to 2023

Protocol summary

Study aim

Investigating the amount of pain and muscle atrophy visible in MRI of patients with non-specific chronic back pain before and after exercise therapy and corrective exercises

Design

This self-controlled clinical trial study will be conducted on people aged 20 to 50 y/o (due to the degeneration process after the age of 50) with non-specific chronic back pain who refer to Imam Khomeini Hospital in Sari Peoplewithnon-specific chronic back pain It includes people who have persistent back pain for more than 3 months without aknownpathoanatomicalcause,theirminimumpain is equal to VAS (Visual analog scale) = 3 and it occurs at least once a week.

Settings and conduct

People aged 20 to 50 with non-specific chronic back pain who refer to Imam Khomeini Hospital in Sari. People with chronic non-specific back pain include people who have persistent back pain for more than 3 months without aknown patho-anatomical cause and at least once in The week will be clear. There is no blinding

Participants/Inclusion and exclusion criteria

Patients with non-specific chronic back pain who do not have the following disorders, including spinal tumor, spinal cord and spine infection, pregnancy, inflammatory lesions of the spine including AS and enthesopathies, previous fracture caused by trauma or tumor, patients with a history of spinal surgery, scoliosis More than 10 degrees, spinalcanalstenosis,spondylolisthesis,patients with psychosis or cognitive disorders in whomneurological examination is not reliable, people who have MRI contraindications,discopathypatients,withdrawal from the study including absence of more than 3 sessions, lack of consent to continue participating in study

Intervention groups

Exercise therapy and corrective movements

Main outcome variables

Severity of pain, neurological deficit

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221101056357N1**
Registration date: **2022-12-05, 1401/09/14**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-05, 1401/09/14**
Update count: **0**

Registration date

2022-12-05, 1401/09/14

Registrant information

Name

sajad najafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 1700

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-11, 1401/08/20

Expected recruitment end date
2023-01-10, 1401/10/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Examining the amount of pain and muscle atrophy visible in MRA of patients with non-specific chronic back pain before and after exercise therapy and corrective exercises in Imam Khomeini Hospital, Sari from 2022 to 2023

Public title
Examining the amount of pain and muscle atrophy visible in MRA of patients with non-specific chronic back pain before and after exercise therapy and corrective exercises in Imam Khomeini Hospital, Sari from 2022 to 2023
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Non-specific chronic back pain patients Absence of spinal tumor Absence of spinal cord and spine infection No pregnancy Absence of spinal inflammatory lesions including AS and enthesopathies Lack of previous fracture caused by trauma or tumor Patients without history of spine surgery Absence of scoliosis more than 10 degrees, spinal canal stenosis Absence of spondylolisthesis Patients with psychosis or cognitive disorders in whom neurological examination is not reliable People who do not have MRI contraindications (phobia, pacemaker...) Patients do not have discopathy Patients with a history of metabolic and hormonal diseases, including acromegaly and hypothyroidism or hyperthyroidism. No diagnosed psychiatric illness such as mood disorders Does not have anxiety disorders, etc., and any neurological and muscular diseases such as dystrophies and other neurological disorders, including MS, ALS, etc.
Exclusion criteria:
Absence of more than 3 sessions Lack of consent to continue participating in the study The occurrence of damage during the study or the creation of a lesion after the start of treatment.
Age
From **65 years** old to **50 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **65**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Imam (RA) Sari Educational and Medical Hospital - Mazandaran University of Medical Sciences (Researc
Street address
Amir Mazandarani Blvd
City
Sari
Province
Mazandaran
Postal code
33131 - 48166
Approval date
2022-07-11, 1401/04/20
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1401.033

Health conditions studied

1

Description of health condition studied
Back ache
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
The amount of pain
Timepoint
Before starting the study and every week for 3 months
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The sports prescription and corrective movements will be 3 sessions per week for 3 months, which will be prescribed for the patients by a doctor of sports physiology and a doctor specializing in sports medicine.
Category
Rehabilitation

2

Description
Control group: The group for physiotherapy will be 3 sessions per week for 3 months, which will be prescribed for patients.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Sajad Najafi
Street address
Neurosurgery Department, Imam Khomeini Hospital, Amir Mazandarani Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saedi
Street address
Mazandaran University of Medical Sciences, Moalem Ave.
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Web page address
https://www.mazums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Sajad Najafi
Position
Associate professo
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available