

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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. People with non-specific chronic back pain. It includes people who have persistent back pain for more than 3 months without a known patho-anatomical cause, their minimum pain 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 a known 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, spinal canal stenosis, spondylolisthesis, patients with psychosis or cognitive disorders in whom neurological examination is not reliable, people who have MRI contraindications, discopathy patients, 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

s.najafi@mazums.ac.ir

##### 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 (Research)

**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.

##### City

Sari

##### Province

Mazandaran

##### Postal code

48166-33131

##### Phone

+98 11 3336 1630

##### Fax

+98 11 3336 1630

##### Email

drsajjad\_najafi@yahoo.com

##### Web page address

<https://www.mazums.ac.ir>

## 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.

##### City

Sari

##### Province

Mazandaran

##### Postal code

48157-33971

##### Phone

+98 11 3325 7230

##### Fax

+98 11 3325 7230

##### Email

m.saedi@mazums.ac.ir

##### 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 professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Neurosurgery

##### Street address

Amir Mazandarani Ave

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Sajad Najafi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Sajad Najafi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

**Street address**

Amir Mazandarani Ave

**City**

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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