

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effect of using MLS laser in reducing pain in patients with chronic low back pain

#### Protocol summary

##### Study aim

Comparison of back pain, EMG/NCS, light touch and pin prick in patients with chronic back pain in two groups before intervention

##### Design

In this random study, double-blind and using a control group of 30 patients with mechanical back pain referred to the clinic of Imam Khomeini Hospital who were diagnosed by a physical medicine specialist based on diagnostic criteria and randomly Two intervention and control groups are divided.

##### Settings and conduct

In this study, two types of exercise therapy protocols will be selected. The first exercise therapy protocol is in accordance with common exercise movements whose effectiveness has been agreed upon and will be recommended to patients in therapy lists. The second protocol also included sports movements that did not have any effect in the treatment of back pain and basically the place of effect is outside the back area. This protocol will be performed as a placebo in the laser group only.

##### Participants/Inclusion and exclusion criteria

Log into: Chronic low back pain Log out: spondylolisthesis and another neurologic disease

##### Intervention groups

The control group of 30 patients with mechanical back pain referred to Imam Khomeini Hospital Clinic In this study, two types of exercise therapy protocols will be selected. The first exercise therapy protocol is in accordance with common exercise movements whose effectiveness has been agreed upon and will be recommended to patients in therapy lists. The second protocol also included sports movements that did not have any effect in the treatment of back pain and basically the place of effect is outside the back area. This protocol will be performed as a placebo in the laser group only.

##### Main outcome variables

The pain Disability Waist movements EMG/NCS Light touch Pin prick

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230827059275N1**

Registration date: **2023-10-23, 1402/08/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-10-23, 1402/08/01**

Update count: **0**

##### Registration date

2023-10-23, 1402/08/01

##### Registrant information

##### Name

sara arefi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3311 3821

##### Email address

arefi.s@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-23, 1402/08/01

##### Expected recruitment end date

2023-12-22, 1402/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of using MLS laser in reducing pain in patients with chronic low back pain

**Public title**

effect of using laser in reducing pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with radicular back pain with age less than 65 years and duration of back pain more than 3 months with or without pain

**Exclusion criteria:**

Simultaneous involvement of nerve roots and neurological and sensory disorders Disorders caused by pressure on the spinal cord such as spondylolisthesis Severe instability of the vertebrae History of back surgery severe osteoporosis Infection at the site of the spinal cord Patient dissatisfaction

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization will be a simple randomization type, where 30 beads of the same shape and size will be selected with black and white color, and then these 30 beads will be mixed and thrown into a non-transparent bag, when the patient visits According to the conditions of entry into the study, a bead is removed from the bag by the researcher, and if the bead is black, the patient will enter the control group, and if the bead is white, the patient will enter the intervention group, and this bead will be kept inside another bag. This will be repeated 30 times.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

For the purpose of blinding, people from the research team who are responsible for the selection and randomization of patients will not enter the other stages of the research, especially the examination of people in terms of the dependent variable. Also, after the consent form was filled and the procedure was explained, the patients and their companions were divided without knowing which of the intervention or control groups they were in. On the other hand, the same placebo will be used in control group patients.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee in Golestan Hospital Research

**Street address**

Golestan Ave, Golestan Hospital, Ahvaz

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135815751

**Approval date**

2022-11-01, 1401/08/10

**Ethics committee reference number**

IR.AJUMS.HGOLESTAN.REC.1401.115

**Health conditions studied****1****Description of health condition studied**

Investigating the effect of using MLS laser in reducing pain in patients with chronic back pain

**ICD-10 code**

M54.5

**ICD-10 code description**

Low back pain

**Primary outcomes****1****Description**

pain

**Timepoint**

start and end of study

**Method of measurement**

VAS

**Secondary outcomes**

empty

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

Intervention group: In this study, two types of exercise therapy protocols will be selected, the first exercise therapy protocol according to the common exercise movements whose effectiveness is agreed upon and will be recommended to patients in the treatment systems.

**Category**

Treatment - Other

**2**

**Description**

Intervention group: Then, the second protocol also includes sports movements that have no effect in the treatment of back pain, and basically the place of effect is outside the back area, which will be performed as a placebo in the laser group only.

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Hospital of Ahvaz

**Full name of responsible person**

Seyed Reza Saedian

**Street address**

Golestan

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135815751

**Phone**

+98 61 3311 3821

**Email**

arefi.s@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mehrnoosh Zakerkish

**Street address**

University of medical science, Golestan street,  
Golestan town, Ahvaz

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135815751

**Phone**

+98 61 3311 3821

**Email**

arefi.s@yahoo.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Seyed Reza Saedian

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

**Street address**

24 metery street, east sahely highway, Ahvaz

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135815751

**Phone**

+98 61 3311 3821

**Email**

saeidian@ajums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Seyed Reza Saedian

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

**Street address**

24 metery street, east sahely highway, Ahvaz

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135815751

**Phone**

+98 61 3311 3821

**Email**

saeidian@ajums.ac.ir

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

Seyed Reza Saedian

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

**Street address**

24 metery street, east sahely highway, Ahvaz

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135815751

**Phone**

+98 61 3311 3821

**Email**

saeidian@ajums.ac.ir

**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 can be shared after de-identifying individuals

**When the data will become available and for how long**

6 months after the results are published

**To whom data/document is available**

Employees in academic institutions

**Under which criteria data/document could be used**

Other data is unpublishable

**From where data/document is obtainable**

sara arefi . arefi.s@yahoo.com

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

Maximum 6 months after email

**Comments**