Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Khouzestan
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

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6135815751

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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

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

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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

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

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Person responsible for updating data

Contact
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Full name of responsible person
Seyed Reza Saedian
Position
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Latest degree
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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 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