

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the effectiveness of laser therapy and physiotherapy in reducing pain in patients with acute low back pain

Protocol summary

Study aim

1. Determining and comparing VAS score in two groups of patients with low back pain treated with physiotherapy and laser therapy
2. Determination and comparison of disability (based on Oswestry Disability Index (ODI) criteria) in two groups of patients with low back pain treated with physiotherapy and laser therapy
3. Determining and comparing the rate of direct lumbar flexion in two groups of patients with low back pain treated with physiotherapy and laser therapy
4. Determining and comparing the rate of lumbar flexion from the right side in two groups of patients with low back pain treated with physiotherapy and laser therapy
5. Determining and comparing the rate of left-back flexion in two groups of patients with low back pain treated with physiotherapy and laser therapy
6. Determining and comparing the amount of rotation to the right of the waist in two groups of patients with low back pain treated with physiotherapy and laser therapy
7. Determining and comparing the amount of left rotation in two groups of patients with low back pain treated with physiotherapy and laser therapy

Design

Clinical trial with control group, with parallel group, randomized, on 60 patients, randomized simple random sampling as a choice

Settings and conduct

Shahid Sadoughi and Shahid Rahnemoun Hospital in Yazd Patients referred to the clinics of these two hospitals were randomly divided into case and control groups and intervened.

Participants/Inclusion and exclusion criteria

Patients with acute low back pain who were willing to participate in the study were included in the study, otherwise, they were not included in the study.

Intervention groups

Control; Treatment with three sessions a week of physiotherapy for one month Case; Treatment with three sessions of laser therapy for one month

Main outcome variables

Achieving a minimally invasive procedure in acute low back pain caused by intervertebral disc herniation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210921052543N1**

Registration date: **2022-02-26, 1400/12/07**

Registration timing: **retrospective**

Last update: **2022-02-26, 1400/12/07**

Update count: **0**

Registration date

2022-02-26, 1400/12/07

Registrant information

Name

Ehsan Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3822 4097

Email address

elastnamejafari@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

2019-09-23, 1398/07/01

Actual recruitment end date

2020-09-22, 1399/07/01

Trial completion date

2020-09-22, 1399/07/01

Scientific title

Comparison of the effectiveness of laser therapy and physiotherapy in reducing pain in patients with acute low back pain

Public title

Evaluating the effect of laser therapy in acute low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients have a history of low back pain for at least 6 weeks All patients with herniated disc pain Use painkillers and rest while studying The patients express their complete desire and satisfaction to enter this project

Exclusion criteria:

Failure to follow physiotherapy and laser therapy sessions for more than one session The treatment plan is changed The patient has other spinal complications The patient has no willingness to continue participating in this project The patient does heavy activities Exit from rest mode The patient has spinal canal stenosis

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Block randomization (patients select in blocks of 5) Randomization unit: Person Randomization tool: Sealed envelopes To concealing random allocation will use Sequentially numbered, sealed, opaque envelopes (SNOSE).

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

Ethics Committee of Shahid Sadoughi University of Medical Sciences

Street address

Department of Physical Medicine and Rehabilitation, Faculty of Medicine, Shahid Sadoughi University of Medical Sciences, Ave. Prof. Hessabi, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

Approval date

2019-07-16, 1398/04/25

Ethics committee reference number

IR.SSU.MEDICINE.REC.1400.109

Health conditions studied

1

Description of health condition studied

acute low back pain, physiotherapy, laser therapy, Oswestry Low Back Disability Questionnaire

ICD-10 code

M54.17

ICD-10 code description

Radiculopathy, lumbosacral region

Primary outcomes

1

Description

Visual Analogue Scale score, Oswestry Disability Index score, back rotation, and flexion score

Timepoint

Completion of the questionnaire at the beginning of the study and the time of the last treatment session

Method of measurement

Comparison of the effect of laser therapy on patient pain; Visual Analogue Scale score, comparison of the effect of laser therapy on the patient's back rotation and flexion; Score based on Likert classification

Secondary outcomes

1

Description

The Oswestry Disability Index

Timepoint

Completion of the questionnaire in the first and last session of treatment

Method of measurement

The Oswestry Disability Index (ODI) is an index derived

from the Oswestry Low Back Pain Questionnaire

Intervention groups

1

Description

Intervention group: Patients with laser therapy - 30 patients with acute low back pain are treated with laser therapy for one month. Treatment sessions are held every other day (15 sessions per month) and each session is 45 minutes.

Category

Rehabilitation

2

Description

Control group: patients with physiotherapy - 30 patients with acute low back pain are treated with physiotherapy for one month. Treatment sessions are held every other day (15 sessions per month) and each session is 45 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadougi Hospital

Full name of responsible person

Ehsan Jafari

Street address

Ave. IBne Sina, Shahid Sadoughi Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

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masoud_mirzaei@hotmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Shahid Sadoughi University of Medical Sciences, Yazd

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

Yazd University of Medical Sciences

Full name of responsible person

Ehsan Jafari

Position

Resident of Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no additional explanation

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable