

# 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

##### City

Yazd

##### Province

Yazd

##### Postal code

##### Phone

+98 35 3822 4000

##### Email

elastnamejafari@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Masoud Mirzaei

##### Street address

Ave. Prof. Hesabi

##### City

Yazd

##### Province

Yazd

##### Postal code

8916978477

##### Phone

+98 35 3724 0171

##### Fax

##### Email

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

##### Street address

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## Person responsible for scientific 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

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Ehsan Jafari

**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