# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Jul 2026

## Comparison of Acupuncture and High Intensity Laser Therapy on Pain, Quality of Life and Disability of Patients with Disc Herniation in Patients with Chronic Low Back Pain, a Randomized Control Study

## Protocol summary


**Study aim**

Comparison of pain and disability and quality of life in patients with disc herniation in patients with chronic low back pain before, 4 weeks and 3 months after starting treatment in three groups under laser treatment, acupuncture and medication (control)

**Design**

The study is a randomized clinical trial with the aim of comparing the therapeutic effects of acupuncture and high power laser in the treatment of patients with disc herniation in patients with chronic low back pain and by simple random allocation method were randomly divided into three groups A, B and C . The sample for each group is 30 people, a total of 90 samples have been calculated for all groups.

**Settings and conduct**

Patients with disc herniation with chronic low back pain are included in the study. Diagnosis will be made using a combination of clinical musculoskeletal and neurological examinations of the lower back and lower limbs. There is no prohibition for the patient to receive the studied interventions.

**Participants/Inclusion and exclusion criteria**

Patients aged 18 to 60 years volunteered to participate in the experiments. They have had back pain for more than 3 months and have local sensitivity in the back, buttocks and legs and shooting pain; Straight Leg Rising (SLR) test or Slump test was positive in lumbar disc herniation MRI and have the mental ability to answer questionnaire questions.

**Intervention groups**

Patients are divided into three groups, including the high-power laser treatment group, the acupuncture treatment group, and the control group treated with medication and exercise.

**Main outcome variables**

Reducing the severity of pain and reducing the degree of disability and improving the quality of life in patients with disc herniation and chronic low back pain in the group receiving high-power laser treatment is more than acupuncture.


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20220506054756N1**
Registration date: **2022-06-17, 1401/03/27**
Registration timing: **prospective**

Last update: **2022-06-17, 1401/03/27**
Update count: **0**

**Registration date**

2022-06-17, 1401/03/27

**Registrant information**


**Name**

Mahin Safari

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-06-22, 1401/04/01

**Expected recruitment end date**

2022-11-21, 1401/08/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of Acupuncture and High Intensity Laser Therapy on Pain, Quality of Life and Disability of Patients with Disc Herniation in Patients with Chronic Low Back Pain, a Randomized Control Study

**Public title**

The Effectiveness of Acupuncture and Laser in Low Back Pain

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients aged 18 to 60 years They signed informed consent forms and volunteered to participate in the experiments They have had back pain for more than 3 months On examination they have local sensitivity in the back, buttocks and legs, and shooting pain, and they have a Straight Leg Rising (SLR) test or a Slump test MRI of the lumbar disc herniation was seen Have the mental ability to answer questionnaire questions

**Exclusion criteria:**

Acute trauma or fracture of the lumbar spine or dysplasia of the spinal structure (spondylolysis) Congenital anomaly, abdominal aneurysm 3. Lumbar spine surgery Uncontrolled or severe metabolic disorders or cardiovascular, hepatic and renal disorders Lumbar spine surgery Uncontrolled or severe metabolic disorders or cardiovascular, hepatic and renal disorders Inflammatory pain Severe or progressive neurological disorders or lumbar instability Physiotherapy treatments on the back in the last 3 months History of lumbar injection in the last 4 weeks Severe osteopenia Systemic rheumatic disease (rheumatoid arthritis and fibromyalgia) Spinal cancers and patients with spinal tuberculosis Danger symptoms include nocturnal pain, recent involuntary weight loss, and symptoms of Cauda equina syndrome Spondylolisthesis Hypersensitivity to piroxicam and methocarbamol Patients who have undergone lumbar spine fusion or have indication for surgery Pregnant patients Patients who have had a tattoo or melanocytic moles in or near the treatment areas Patients with lupus or any other autoimmune disease, thrombophlebitis or anemia, and skin allergies Not participating in treatment sessions for more than 2 sessions Dissatisfaction with participating in the study at any stage of the study No referral for follow-up 4 weeks later and no phone response 3 months after starting treatment Emergence of severe medical diseases during the study that affect the individual's referral and follow-up

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients after selecting and obtaining informed consent to participate in the study after explaining the steps of the study, by simple random allocation using a table of random numbers by computer and online) using the site (www.random.org/ integres as Randomly divided into three groups A, B and C. Patients were divided into three groups, each with its own code, which were written on the sheets in which the patient group was identified. The codes placed patients in one of three groups by selecting each envelope.

**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 Mazandaran University of Medical Sciences

**Street address**

Mazandaran University of Medical Sciences, beginning of Vali Asr Highway, Joybar Three Ways,Imam Square, Sari, Mazandaran, Iran

**City**

Sari

**Province**

Mazandaran

**Postal code**

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**Approval date**

2022-06-01, 1401/03/11

**Ethics committee reference number**

IR.MAZUMS.REC.1401.065

## Health conditions studied

**1**

**Description of health condition studied**

Lumbar disc herniation, chronic low back pain, sciatica

**ICD-10 code**

M54.40

**ICD-10 code description**

Lumbago with sciatica, unspecified side

## Primary outcomes

### 1

**Description**
Pain intensity, quality of life, degree of disability in patients with chronic low back pain

**Timepoint**
Initially studied, 4 weeks and three months after starting treatment

**Method of measurement**
McGill Pain Questionnaire ,Oswestry Low Back Pain Disability Questionnaire, WHO Quality of Life, Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: In the high-power laser intervention group, high-power laser treatment patients will receive high-power laser from the device manufactured by Novin Company. The device provides the following options: high-power laser with pulse emission (808 nm), very high peak power (1500 mW), frequency 100 Hz, energy density 1200 mJ / cm2 energy density), pulse duration 8:30 minutes, Work cycle about 0.1%, probe diameter 0.5 cm and spot size 0.2 cm2. While the patient is lying down, the handpiece will be treated in contact and perpendicular to the area. The laser will be applied transversely and longitudinally to the back of the waist in the paraspinal region, lower back, quadriceps and buttocks. Also includes hotspots and trigger points. This procedure is repeated three times a week (10 sessions in total)

**Category**
Rehabilitation

### 2

**Description**
Intervention group: Proximal and distal lumbar points are selected in the acupuncture treatment group. After disinfecting the skin with alcohol, the needle with a length of 25 and a diameter of 0.30 mm will be placed in the points ST36 GB30, GB34, BL25, BL23. In addition to the acupuncture mentioned, acupuncture is performed on the trigger points of the waist in each session. All needles are manipulated at 45 degrees clockwise and counterclockwise and held for 15 minutes. This procedure is repeated three times a week (10 sessions in total).

**Category**
Rehabilitation

### 3

**Description**
Control group: Control group: The group was treated with medication and exercise. The method of exercising was designed to be easily done at home. The exercises will be performed with the aim of increasing flexibility, endurance, strength, stability and painless mobility, as well as controlling the posture of the lumbar spine. General exercises and central stabilization are performed on the muscles responsible for central stabilization, and according to the patient's tolerance, gentle stretching of the lumbar, hip and thigh muscles is performed in the same way for all patients. All treatment groups will be given the same instructions to exercise three times a day for 4 weeks. Medication also includes 2 capsules of piroxicam once a day (a total of 20 mg and methocarbamol 500 mg tablets three times a day for 2 weeks. During this time, follow-up exercise and medication will be done by phone). became.

**Category**
Rehabilitation

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Imam Khomeini Hospital, Sari

**Full name of responsible person**
Mahin Safari

**Street address**
Sports Medicine Department, Mostafavian Clinic, Razi St., Sari, Mazandaran, Iran

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Mazandaran University of Medical Sciences

**Full name of responsible person**
Dr. Younes Panahi

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http://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**
Mahin Safari
**Position**
Sports medicine resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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 potential personal data is shared after individuals are not identified.

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

Access starts 6 months after the results are published

**To whom data/document is available**

For researchers working in academic and scientific institutions

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

For researchers working in academic and scientific institutes, in order to conduct further studies in the future, the study method and study statistical data are available.

**From where data/document is obtainable**

Mahin Jafari Kakroodi 1368@yahoo.com; Dr. Mahin Safari 00981133366552

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

After receiving the documentation request email, the data file will be sent.

**Comments**