

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effects of Laser Disc Decompression in Patients with Lumbar Disc Herniation: A Clinical Trial

#### Protocol summary

##### Study aim

Study and investigate the therapeutic effects of laser disc decompression in disc herniation

##### Design

The present clinical study was performed on 58 patients referred to the hospital from 2019 to 2020 who underwent percutaneous laser disc decompression (PLDD). Which included all eligible people over the age of 18 who met The Inclusion & Exclusion Criteria

##### Settings and conduct

Operating Room. Blinding has not been done. The present clinical trial has been done on 58 patients underwent PLDD. Patients were treated with PLDD according to the protocol and were monitored before and after treatment

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Eligible patients are patients over 18 years of age with radiologic compact disc herniation and lumbosacral radicular syndrome lasted for 6-8 weeks or herniated segment should be less than 1/3 of the spinal canal based on the patient's MRI or CT-Scan. They were treated with PLDD according to the treatment protocol and were monitored before and after treatment using the visual analogue scale (VAS). We also excluded all the patients who have had Cauda Equina syndrome, previous spine surgery at the same disk level, spondylolisthesis, spinal stenosis, pregnancy, and severe physical and mental illness over the past year

##### Intervention groups

microdiscectomy was performed by an ipsilateral approach with retraction of mid-line paravertebral muscles without bone removal or with small bone removal and Displacement of the herniated disc through the transflaval. In PLDD, laser energy was sent using an optical fiber inserted through a 18G needle inserted into the pulposus nucleus via an articular graft from the posterolateral side. The procedure was performed with local anesthesia without the need for an

anesthesiologist. Eventually, as the nucleus of the disk drains, the pressure on the nerve was reduced.

##### Main outcome variables

VAS Before VAS After

#### General information

##### Reason for update

##### Acronym

Percutaneous Laser Disc Decompression Trial

##### IRCT registration information

IRCT registration number: **IRCT20200807048332N1**

Registration date: **2020-10-14, 1399/07/23**

Registration timing: **retrospective**

Last update: **2020-10-14, 1399/07/23**

Update count: **0**

##### Registration date

2020-10-14, 1399/07/23

##### Registrant information

##### Name

Şeyed Ghavam Shafagh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2238 6159

##### Email address

ghshafagh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-27, 1398/03/06

##### Expected recruitment end date

2020-04-29, 1399/02/10

##### Actual recruitment start date

2019-05-27, 1398/03/06  
**Actual recruitment end date**  
2020-04-29, 1399/02/10  
**Trial completion date**  
2020-04-29, 1399/02/10

**Scientific title**  
Effects of Laser Disc Decompression in Patients with Lumbar Disc Herniation: A Clinical Trial

**Public title**  
Using therapeutic laser for treating herniated intervertebral disc

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Eligible patients were patients over 18 years of age with radiologic Compact Disc herniation Lumbosacral radicular syndrome lasted for 6-8 weeks Herniated segment should be less than 1/3 of the spinal canal based on the patient's MRI or CT-Scan

**Exclusion criteria:**  
All the patients who have had Cauda Equina syndrome Previous spine surgery at the same disk level Pregnancy Spinal stenosis spondylolisthesis Severe physical and mental illness over the past year

**Age**  
From **49 years** old to **77 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **75**  
Actual sample size reached: **58**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**  
**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**  
**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**  
**Name of ethics committee**  
AJA University of Medical Sciences ethical committee  
**Street address**

Etemad Zadeh Street  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1411718541

**Approval date**  
2020-10-12, 1399/07/21  
**Ethics committee reference number**  
IR.AJAUMS.REC.1399.125

## Health conditions studied

### 1

**Description of health condition studied**  
Herniated Disc  
**ICD-10 code**  
M50  
**ICD-10 code description**  
Cervical disc disorders

### 2

**Description of health condition studied**  
Herniated Disc  
**ICD-10 code**  
M51  
**ICD-10 code description**  
Thoracic, thoracolumbar, and lumbosacral intervertebral disc disorders

### 3

**Description of health condition studied**  
Herniated Disc  
**ICD-10 code**  
G55  
**ICD-10 code description**  
Nerve root and plexus compressions in diseases classified elsewhere

## Primary outcomes

### 1

**Description**  
The cost of treatment  
**Timepoint**  
At the first of the study  
**Method of measurement**  
Payments

### 2

**Description**  
Comparison The Pain and Disability before and after the Procedure  
**Timepoint**  
Before and After the procedure  
**Method of measurement**

Verbal and Visual Analogue Scale By stimulating the pain, we ask the patient to give us a score from 0 to 10, and from the patient's facial expression

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The present clinical study was performed on 58 patients referred to the hospital from 2019 to 2020 who underwent percutaneous laser disc decompression (PLDD). Inclusion criteria: Eligible patients were patients over 18 years of age with radiologic Compact Disc herniation, and lumbosacral radicular syndrome lasted for 6-8 weeks, or herniated segment should be less than 1/3 of the spinal canal based on the patient's MRI or CT-Scan. According to the treatment protocol, they were treated with PLDD and were monitored before and after treatment using the Verbal and Visual Analogue Scale (VAS). We also excluded all the patients who have had Cauda Equina syndrome, previous spine surgery at the same disk level, spondylolisthesis, spinal stenosis, pregnancy, and severe physical and mental illness over the past year. PLDD Treatment Protocol: In brief, microdiscectomy was performed by an ipsilateral approach with retraction of mid-line paravertebral muscles without bone removal or with small bone removal and Displacement of the herniated disc through the transflaval. In PLDD, laser energy was sent using an optical fiber inserted through an 18G needle inserted into the pulposus nucleus via an articular graft from the Posterolateral side. The procedure was performed with local anesthesia without the need for an anesthesiologist. Eventually, as the nucleus of the disc drains, the pressure on the nerve was reduced. The patients first located in the prone position. The patients were prepared after prepping and draping, and under the C-Arm X-Ray machines (CARM) guide from the lateral Scottish dog to the desired level of the symptomatic side, needle gage 18 is entered as the tunnel view. After discography and control at the Antero-Posterior and Lateral aspects and ensure that the needle is in the middle of the disc, the fiber (980 nm wavelength and 240-400 µm diode laser) is entered into the needle. Y connector is closed, and then we set the device to 8 Joules and adjust the settings in 0.6-second radiation and 1.2 seconds pause; also, we set the device to 8 watts in active mode, then we press the pedal, and irradiated from 800 to 1400 joules depending on the size of the disc and its level, and usually at every 300 joules, the needles will be pulled up to 2 mm backward or forward to create a larger quadrant. If the patient is found to have radicular pain, the needle will be moved with control by CARM; it is normal to have mild lumbar pain (measuring the pain by pain score). The patient has to be alert and conscious at all stages of the procedure and initially has a slight sedation when asked to move his/her

feet during surgery. The surgery is performed by an experienced neurosurgeon and was observed by other experts

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mostafa Khomeini Hospital

##### Full name of responsible person

Dr Sharif Najafi

##### Street address

Keshavarz Boulevard and west of Palestine Street and east of Vesal Street and north of Taleghani Street, north of Italy Street

##### City

Tehran

##### Province

Tehran

##### Postal code

1997723581

##### Phone

+98 21 8896 6130

##### Fax

##### Email

nadarand@yahoo.com

##### Web page address

[http://mkht.ir/index.php?option=com\\_content&view=article&id=49:%D8%AA%D9%84%D9%81%D9%86-%D9%87%D8%A7%DB%8C-%D8%B6%D8%B1%D9%88%D8%B1%DB%8C-%D9%88-%D8%A2%D8%AF%D8%B1%D8%B3-%D8%A8%DB%8C%D9%85%D8%A7%D8%B1%D8%B3%D8%AA%D8%A7%D9%86&catid=10&lang=fa&Itemid=201](http://mkht.ir/index.php?option=com_content&view=article&id=49:%D8%AA%D9%84%D9%81%D9%86-%D9%87%D8%A7%DB%8C-%D8%B6%D8%B1%D9%88%D8%B1%DB%8C-%D9%88-%D8%A2%D8%AF%D8%B1%D8%B3-%D8%A8%DB%8C%D9%85%D8%A7%D8%B1%D8%B3%D8%AA%D8%A7%D9%86&catid=10&lang=fa&Itemid=201)

### 2

#### Recruitment center

##### Name of recruitment center

Shahram Hospital

##### Full name of responsible person

Dr Sharif Najafi

##### Street address

No1, Corner of Chehelsotoun St, Dr Fatemi Sq

##### City

Tehran

##### Province

Tehran

##### Postal code

1431694411

##### Phone

+98 21 8895 7170

##### Email

Shahram.Hospital@gmail.com

##### Web page address

<http://shahramhospital.ir/contact/>

### 3

#### Recruitment center

**Name of recruitment center**

Golestan Hospital

**Full name of responsible person**

Dr Sharif Najafi

**Street address**

Sayad Shirazi Highway, Pasdaran Crossroads

**City**

Tehran

**Province**

Tehran

**Postal code**

166861955

**Phone**

+98 21 2254 9002

**Email**

info@golestanhospital.com

**Web page address**

<https://golestan.ajaums.ac.ir/page/addr/>

### 4

#### Recruitment center

**Name of recruitment center**

Moheb Kousar Hospital

**Full name of responsible person**

Dr Sharif Najafi

**Street address**

23rd St, Yousef Abad St

**City**

Tehran

**Province**

Tehran

**Postal code**

1433933118

**Phone**

+98 21 4219 3000

**Email**

info@kowsarhospital.com

**Web page address**

<http://www.kowsarhospital.com/fa/contactus/contactus-%d8%aa%d9%85%d8%a7%d8%b3-%d8%a8%d8%a7-%d8%a8%db%8c%d9%85%d8%a7%d8%b1%d8%b3%d8%aa%d8%a7%d9%86>

### 5

#### Recruitment center

**Name of recruitment center**

Khatam-al- Anbya Hospital

**Full name of responsible person**

Dr Sharif Najafi

**Street address**

Rashid Yasemi Street, Upper than Mirdamad St., Vali-Asr S

**City**

Tehran

**Province**

Tehran

**Postal code**

1996835911

**Phone**

+98 21 8888 4040

**Email**

info@khatamhospital.com

**Web page address**

<https://www.khatamhospital.org/news.php?page=157>

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Dr Sharif Najafi

**Street address**

Etemad Zadeh St

**City**

Tehran

**Province**

Tehran

**Postal code**

1411718541

**Phone**

+98 21 8609 6350

**Email**

info@ajaums.ac.ir

**Web page address**

<https://www.ajaums.ac.ir/>

**Grant name**

Vice Chancellor for Research, AJA University of Medical Sciences, Dr. Sharif Najafi

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Artesh 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**

Iran University of Medical Sciences

**Full name of responsible person**

Seyed Ghavam Shafagh

**Position**

general practitioner

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

No 8, 4th east Ave, 24 metri Blvd, sadat abad

**City**

Tehran

**Province**

Tehran

**Postal code**

1997758540

**Phone**

+98 21 2238 6159

**Email**

ghshafagh@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Boustani

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Spine Surgery Fellowship

**Street address**

No 8, 4th east Ave, 24 metri Blvd, sadat abad

**City**

Tehran

**Province**

Tehran

**Postal code**

1997758540

**Phone**

+98 21 2238 6159

**Email**

Dr.boustani@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Seyed Ghavam Shafagh

**Position**

general physician

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

No 8, 4th east Ave, 24 metri Blvd, Sadat abad

**City**

Tehran

**Province**

Tehran

**Postal code**

1997758540

**Phone**

+98 912 424 5334

**Email**

ghshafagh@gmail.com

**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**

Ethical issues

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available