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

Ŝeyed 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

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