Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of High Intensity Laser Plus Manual Therapy versus Manual Therapy alone on Pain and Function in Patients with Cervical Radiculopathy cause by Disk Herniation

Protocol summary

Study aim
Determination effects of High Intensity Laser Plus Manual Therapy versus Manual Therapy alone on Pain and Function in Patients with Cervical Radiculopathy cause by Disk Herniation

Design
Clinical trial with a control group, double blind, randomized, on 48 patients. The 4 block method is used for randomization.

Settings and conduct
Patients will be entered into the clinical trial based on the inclusion criteria. They read and sign the informed consent form before starting the intervention, then the general information, pain and disability questionnaires will be completed. muscle activity will be recorded by surface electromyography device. images of the deep flexor muscles of the neck will be evaluated by ultrasonography device.Then the patients will be randomly assigned to one of two groups. this trial will be performed in the physiotherapy clinic, school of rehabilitation sciences, zahedan university of medical sciences.

Participants/Inclusion and exclusion criteria
People with discopathy C6 and C7, age 20 and 55 years, conflict over three months, history of migraine, the presence of fracture in the spine

Intervention groups
The control group that receives myofascial release technique, nerve mobilization, chin tuck exercise and strengthening and stretching exercises for shoulder girdle muscles three times a week for 6 weeks; Intervention group(manual therapy and high intensity laser) that receives the protocol of manual therapy and exercise therapy same as the control group. In addition to this protocol, they also receive high- intensity laser. In this study, high- intensity laser device with maximum output of 20 watt is used. Treatment in this group is done three times a week for 6 weeks.

Main outcome variables
Pain; disability

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220626055278N2**
Registration date: **2022-08-25, 1401/06/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-25, 1401/06/03**
Update count: **0**

Registration date
2022-08-25, 1401/06/03

Registrant information

Name
Hassan Namvar

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-22, 1401/05/31

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
Effects of High Intensity Laser Plus Manual Therapy versus Manual Therapy alone on Pain and Function in Patients with Cervical Radiculopathy cause by Disk Herniation

Public title
Effects of High Intensity Laser and Manual Therapy in Patients with Disk Herniation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People with cervical radiculopathy caused by disc herniation in C6 and C7 roots Age between 20 and 55 years The presence of conflict for more than three months
Exclusion criteria:
Known history of migraine Presence of thoracic outlet syndrome The presence of fracture in the spine during the last 6 months The presence of tumor in the spine Musculoskeletal disorders of the shoulder area such as tendonitis and bursitis Rheumatoid inflammatory diseases Pregnancy Simultaneous pain in other areas of the spine such as back pain and radiculopathy in the area of the lumbar spine History of whiplash injury History of any shoulder and neck surgery in the past 6 months Peoples unwillingness to participate in the study Receiving any type of physical therapy treatment in the past month
Age
From **20 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
In the present study, sampling is non probability and easy or available sampling. Allocation of patients to two groups of manual therapy and laser therapy (experimental group) or manual therapy alone (control group) is done based on random block method (block size of 4 and allocation ratio 1:1). in this way, at the end of all four samplings, the number of samples in both groups is equal.
Blinding (investigator's opinion)
Double blinded
Blinding description
The participant will not know the type of treatment and the number of treatment groups.The researcher will not know which treatment group the patient is in, the high intensity laser will be performed by one therapist and the manual therapy will be performed by another therapist. The evaluator will not know the type of treatment performed on the patient.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Ghods Street, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1417653911
Approval date
2022-07-16, 1401/04/25
Ethics committee reference number
IR.TUMS.FNM.REC.1401.050

Health conditions studied

1

Description of health condition studied
Disc herniation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain: according to the definition of the International Pain Association, pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage.
Timepoint
Before the start of the intervention and six weeks after the intervention and two months after the end of treatment
Method of measurement
Visual Analogue Scale. The people participating in the

study are asked to determine the level of their neck pain on a chart where the number 0 indicates the lowest level of pain and the number 10 indicates the highest level of pain.

2

Description
Disability: any lack or limitation in the ability to perform activities that are normally expected of any person, is called disability.
Timepoint
Before the start of the intervention and six weeks after the intervention and two months after the end of treatment
Method of measurement
Disability is measured by two questionnaires, Neck disability index and Neck pain and disability scale.

Secondary outcomes

1

Description
Imaging the deep flexor muscles of the neck: the images of the deep flexor muscles of the neck, including longus colli and longus capitis, are evaluated both in the transverse view and in the longitudinal view.
Timepoint
Before the start of the intervention and six weeks after the intervention and two months after the end of treatment
Method of measurement
Ultrasonography device

2

Description
Recording the electrical activity of the flexor carpi radialis muscle
Timepoint
Before the start of the intervention and six weeks after the intervention and two months after the end of treatment
Method of measurement
Surface electromyography device

Intervention groups

1

Description
Control group: Treatment protocol for the control group (alone manual therapy) that will receive three times a week for 6 weeks: 1- myofascial release technique: this technique is one of the manual therapy techniques that is done with the aim of stretching and relaxing the fascia and muscles to reduce pain and improve performance. This technique is applied for 10 minutes by the therapist on the tissues of the neck and shoulder girdle. 2- nerve mobilization: in this study, radial and median nerve mobilization is performed and the range of techniques is increased by the therapist according to the patients condition during the sessions. 3- chin tuck exercise: people are asked to perform head flexion with the aim of stretching the suboccipital muscles and activating the deep flexor muscles 5 times a week, 10-15 repetitions, with 10 second hold and 10 second rest. 4- strengthening and stretching exercises for shoulder girdle muscles: people are taught strengthening exercises for the scapula retractor muscles and stretching of the upper trapezius, scalene and sternocleidomastoid muscles.
Category
Rehabilitation

2

Description
Intervention group: Test group (manual therapy and high intensity laser): People in this group, will receive the same protocol of manual therapy and exercise therapy as the control group 3 times a week for 6 weeks. In addition, in this group, people are treated with high-intensity laser. In this study, high- intensity laser device, k-laser series 4, with maximum output of 20 watts, made in Italy, is used. This laser has 4 wavelengths 660, 800, 905, 970 nanometers. To perform the laser, the patient is placed in prone position and the laser application technique is scanning around the cervical vertebrae and the total time of laser treatment is five minutes and eight seconds and the total energy received by the tissue, is 2975 joules. The application program includes 11 phases, the first and last phases are continuous waves and the phases between them are pulses. Befor laser irradiation the treatment area will be completely cleaned with alcohol to minimize the amount of skin resistance caused by fat on the skin and the reflection of laser beams from the skin surface. During the treatment, both the therapist and the patient will use special glasses to prevent eye damage.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Razmjoomoghadam Physiotherapy Clinic
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
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Namvar hasan
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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