

# 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

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**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**

Sargolzehi Maryam

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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

**Full name of responsible person**

Namvar hasan

**Position**

Student

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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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