Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

The Effects of High Intensity Laser on Clinical and Electrophysiological Findings of Unilateral Cervical Radiculopathy Due to Disc Protrusion: A Triple Blind Randomized Clinical Trial Study

Protocol summary

Study aim

Investigating the effects of high intensity laser on clinical and electrophysiological findings of unilateral cervical radiculopathy patients due to disc protrusion

Design

A placebo controlled triple Blind Randomized Clinical Trial Study on 30 patients with blinded patients, assessors and therapist. The simple randomization method will be used with randomization list generated by Excel Office 2010.

Settings and conduct

30 eligible patients will be allocated randomly into active HIL plus routine physiotherapy (n=15) or placebo HIL plus routine physiotherapy group (n=15) by a researcher who is not involved with the recruitment and evaluation of patients. This same researcher is the only person that aware of patients allocation to their treatment groups and will be responsible for programming the HIL device according to the result of the randomization. Assessment of clinical and electrophysiological outcomes will be performed at pre-intervention, the end of the 10 treatment sessions and 1 month follow-up. Eventually, collected data will be analyzed by a statistician.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 20-55 years; neck pain visual analogue score of 3-7; radicular pain and/or paresthesia in affected upper limb; C5-C6،C6-C7،C7-C8 and C8-T1 disc protrusion confirmed by MRI

Intervention groups

Eligible unilateral cervical radiculopathy due to disc protrusion patients will be randomly divided into two groups. In group 1, patients will receive HILT plus routine physiotherapy, while in group 2, placebo laser plus routine physiotherapy will be applied.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180721040539N2**
Registration date: **2020-12-08, 1399/09/18**
Registration timing: **prospective**

Last update: **2020-12-08, 1399/09/18**
Update count: **0**

Registration date

2020-12-08, 1399/09/18

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effects of High Intensity Laser on Clinical and Electrophysiological Findings of Unilateral Cervical Radiculopathy Due to Disc Protrusion: A Triple Blind Randomized Clinical Trial Study

Public title
The Effects of High Intensity Laser on Clinical and Electrophysiological Findings of Unilateral Cervical Radiculopathy Due to Disc Protrusion

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Aged 20-55 years Neck pain visual analogue score of 3-7 Radicular pain and/or paresthesia in affected upper limb C5-C6، C6-C7 ،C7-C8 and C8-T1 disc protrusion confirmed by MRI Diagnosed unilateral cervical radiculopathy due to disc protrusion by a neurology specialist based on nerve conduction study (NCS) and electromyography (EMG) Symptoms lasting for at least 3 months Positive Spurling compression test Positive Median nerve tension test

Exclusion criteria:
Inflammatory diseases such as rheumatoid arthritis Viral, fungal, and bacterial infections Systemic and metabolic diseases History of neck surgery Abnormal laboratory findings Psychiatric illnesses Photosensitive diseases Trauma and fracture in cervical spine Fibromyalgia Active cancer or a cancer history of less than 1 year after the end of treatment Epilepsy Upper limb peripheral nerves entrapment syndromes Tumor Muscle weakness Loss of reflex Cervical disc extrusion and sequestration Atrophy Metal implants Skin lesions in the treatment area Pregnancy Degenerative changes of cervical or thoracic region Cardiovascular failure Pacemaker Decreased motor nerves amplitude in electrophysiological findings

Age
From **20 years** old to **55 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomized into one of the intervention groups. The simple randomization method will be used; Randomization list will be generated by a computer program (Excel Office 2010) by a statistician and performed by a participating researcher not involved with the recruitment or evaluation of patients. This same researcher will be responsible for programming the HIL device according to the result of the randomization. The HIL device used in the present study will make the same sounds regardless of the programmed dose and mode (active HIL or placebo HIL). This researcher will not disclose the programmed intervention (active HIL or placebo HIL) to the therapist or any of the patients and other researchers involved in the study until its final completion. Concealed allocation will be achieved through the use of sequentially numbered, sealed and opaque envelopes.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Initially the patients will be visited by the first study's blinded assessor (neurology specialist) who will determine eligible participants based on inclusion and exclusion criteria and will obtain the electrophysiological outcomes. Next, the second study's blinded assessor (physiotherapy specialist) will collect the clinical outcomes. Then all eligible patients will be randomized and allocated into two treatment groups (active HIL or placebo HIL) by a researcher who is not involved with the recruitment or evaluation of patients. This same researcher is the only person that aware of patients allocation to their treatment groups and will be responsible for programming the HIL device according to the result of the randomization. This researcher will not disclose the programmed intervention to the therapist or any of the patients and other researchers involved in the study until its final completion; Thus Patients, therapist and assessors will be blinded throughout the study. Assessment of clinical and electrophysiological outcomes at the end of the 10 treatment sessions and 1month follow-up will be performed by the same assessors who carried out the first evaluations. Eventually, collected data will be analyzed by a statistician.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Babol University of Medical Sciences

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Babol university of medical science, Ganjafrouz Ave

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Mazandaran

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47176-47745

Approval date
2020-09-19, 1399/06/29
Ethics committee reference number
IR.MUBABOL.REC.1399.291

Health conditions studied

1

Description of health condition studied
Unilateral cervical radiculopathy due to disc protrusion
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain
Timepoint
Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session
Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
Radicular pain and/or paresthesia in affected upper limb
Timepoint
Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session
Method of measurement
Short-Form McGill pain questionnaire (SF-MPQ-2)

2

Description
Functional disability
Timepoint
Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session
Method of measurement
Neck disability index questionnaire

3

Description
Neck active range of motion including flexion, extension, lateral flexion (both sides), rotation (both sides)
Timepoint
Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session
Method of measurement
Standard plastic goniometer

4

Description
Median nerve tension
Timepoint
Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session
Method of measurement
Median nerve tension test

5

Description
Electrophysiological parameters including motor distal latency, motor nerve conduction velocity and F-wave of radial, ulnar, median motor nerves
Timepoint
Prior to treatment initiation, at the end of the 10 treatment sessions and 1month after the completion of last treatment session
Method of measurement
Electrodiagnosis device Negarandishegan-EMG/NCV/EP400S

Intervention groups

1

Description
Active HIL group: HIL will be applied using the Delta Laser New Age device (Italy) with a wavelength of 980 nm and 13 W maximum power output with probe diameter of 1 cm. The treatment will be consisted of three phases in each session. The initial phase will involve a peak power of 13 W, average power of 6/5 W and 1852 J energy.The intermediate phase will be applied a peak power of 11 W, average power of 5/5 W and 1574 J energy. The final phase will be performed with a peak power of 13 W, average power of 6/5 W and 1852 J energy the same as the initial phase. HIL treatment will be included 15 min application time (each phase 5 min), duty cycle of 50% (in all 3 phases) and total energy of 5278 J in each session. Probe will be held in contact with the dry skin previously cleaned with alcohol, at 90 degree angle perpendicular to the paraspinal muscles above the transverse processes of each of the cervical and upper thoracic vertebrae in affected side which will be consisted 30 cm2 treatment area. The hand piece will be moved in a parallel slow motion to the intended muscle fibers.
Category
Rehabilitation

2

Description
Placebo HIL Group: The placebo HIL will be applied on the same irradiated sites in the active HIL group using the same device that activates HIL but without any emission of therapeutic dose. Thus patients will receive a total dose of 0 J in placebo mode. The active and placebo HIL procedures will be performed in the prone position

with slightly flexion in cervical spine and also laser protective goggles will be used in both groups. To ensure blinding for therapist and patients, the device will emit the same sounds regardless of the programmed mode (active or placebo). Furthermore, because the device produces a non-significant amount of heat, the patients will not be able to know if active or placebo HIL will be administered. The device was previously coded as active or placebo modes, and only one researcher not involved in the evaluation and treatment is aware of these codes. Patients will undergo treatment (active HIL or placebo) according to prior randomization, three times a week on even days, for 10 sessions totally. Ultrasound and TENS therapy will be done similarly in both groups. Ultrasound therapy will be performed in prone position by the apparatus Novin 215P (Iran), frequency of 1 MHz, intensity of 1/5 w/cm, duty cycle of 50% and treatment time of 5 minutes. Surface of US probe covered with conductivity gel will be moved on the cervical paraspinal muscles in affected side with the slow circular movements. TENS application will be applied in supine position by the stimulator device Novin 735X (Iran) in conventional mode for 20 min at 70-Hz frequency and 100-µs wavelength. Four 4×6 electrodes stimulator device will be placed in a standardized dermatomal pain pattern. The intensity of the electrical stimulation will be adjusted to the maximum tolerated amplitude without producing muscle contractions.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Omid Government super specialty 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
Babol 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
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Full name of responsible person
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Position
Master’s Degree student

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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