

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Short Term Effects of Low versus High Power Lasers on Soreness following Dry Needling at Neck Myofascial Pain Syndrome induced by Active Trigger Points of Upper Trapezius Muscle.

Protocol summary

Study aim

1- Comparison of Low Level Laser Therapy (LLLT) and High Level Laser Therapy (HLLT) on postneedling soreness on patient with chronic neck pain 2- Investigate and comparison of the immediate and long term effects of different kinds of laser (LLLT, HLLT & Placebo) and Dry needle (DN) accompaniment on improvement of chronic neck myofascial pain syndrom

Design

A randomized, double blind, controlled clinical trial with a parallel group design

Settings and conduct

The study is being conducted in the Physiotherapy Clinic of the Faculty of Rehabilitation. Inclusion and exclusion criteria are checked and written consent is obtained from all individuals. Patients are randomizing with the Balance Block method. In this study, the assessor and the patients are blind.

Participants/Inclusion and exclusion criteria

Chronic cervical pain (3 months or more) due to myofascial pain syndrome and the presence of a tender point in taut band in the upper trapezius muscle that causes pain in response to compression relies on inclusion criteria. People with any psychologic disorders, a history of stress last week, cervical radiculopathy pain , dizziness, neck surgery, and any type of contraindications of dry needle are excluded from the study.

Intervention groups

In all groups, the trigger point is first treated with a dry needle. After applying dry needle, the laser is irradiated. In the low-power laser group, a laser with a power of 100 miliWatts/cm² and an energy of 6 jules, in the group of high-power lasers, a laser with a power of 1 watt/cm² and a power of 6 jules, and in the control group, the probe is kept off for 1 minute.

Main outcome variables

Pain pressure threshold in cervical region for assessing soreness (by algometer), pain of palpation for assessing soreness (by VAS scale), neck pain (by VAS scale), cervical range of motion (by goniometer), and disability (by Neck disability index)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190411043241N1**

Registration date: **2019-09-02, 1398/06/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-02, 1398/06/11**

Update count: **0**

Registration date

2019-09-02, 1398/06/11

Registrant information

Name

Maryam Motavalian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-30, 1398/04/09

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Short Term Effects of Low versus High Power Lasers on Soreness following Dry Needling at Neck Myofascial Pain Syndrome induced by Active Trigger Points of Upper Trapezius Muscle.

Public title

Use of laser beams on postneedling soreness and treatment of chronic cervical pain

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Females aged 18-35 years old Cervical pain lasting for 3 months or more Neck pain intensity of at least 3 points based on the VAS scale Presence of a palpable taut band in the muscle Presence of a hypersensitive tender spot in the taut band Local or referred pain elicitation in response to compression

Exclusion criteria:

Contraindications of dry needling(cancer, presence of coagulation and vascular disorders, Pregnancy, epilepsy, fibromyalgia, needle aversion or phobia) Significant psychological disorders Stress in the last week Cervical radiculopathy pain Dizziness History of cervical surgery

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced Block Randomizatin

Blinding (investigator's opinion)

Double blinded

Blinding description

Using laser off in the placebo group will cause blindness to the participants. Assessor will not be aware about patient's group, because assessment will do in another room.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of nursing and midwifery and rehabilitation schools of Tehran University of Medical

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Ghods Ave , Keshavarz Blvd

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1417653761

Approval date

2019-06-25, 1398/04/04

Ethics committee reference number

IR.TUMS.FNM.REC.1398.054

Health conditions studied**1****Description of health condition studied**

Active Trigger Points in Upper Trapezius Muscle

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain of palpation

Timepoint

Before intervention, immediately after, 24 and 48 hours after intervention

Method of measurement

Visual Analogue Scale

2**Description**

Pain Pressure Threshold

Timepoint

Before intervention, immediately after, 24 and 48 hours after intervention

Method of measurement

By using algometer

Secondary outcomes**1****Description**

General pain

Timepoint

Before intervention, immediately after, 24 and 48 hours after intervention

Method of measurement

Visual Analogue Scale

2

Description

Cervical range of motion

Timepoint

Before intervention, immediately after and 48 hours after intervention

Method of measurement

By using a goniometer

3

Description

Neck disability

Timepoint

Before intervention and 48 hours after intervention

Method of measurement

Neck Disability Index

Intervention groups

1

Description

Intervention group: High Power Laser: In this group, the dry needle is applied to the most active trigger point in the upper trapezius muscle. Immediately a laser with a power of 1 watts / cm² is applied for 6 seconds and with a total energy of 6 joules .

Category

Treatment - Devices

2

Description

Intervention group: Low Power Laser: In this group, the dry needle is applied to the most active trigger point in the upper trapezius muscle. Immediately a laser with a power of 100 miliwatts / cm² is applied for 60 seconds and with a total energy of 6 joules .

Category

Treatment - Devices

3

Description

Control group: Sham Laser: In this group the dry needle is applied to the most active trigger point in the upper trapezius muscle. Immediately the off laser probe will be use at the point for 1 minute .

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Clinic of Tehran University of Medical Sciences

Full name of responsible person

Seyyed Mohsen Mir

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Department of Physiotherapy ,School of Rehabilitation,Pitch-e Shemiran, Enghelab Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Saharian

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Vice chancellor for research of Tehran University of Medical Science,6th floor, University central office ,Ghods Avenue,Keshavarz Blv

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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

Maryam Motavalian

Position

Master student of Physical therapy

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Full name of responsible person

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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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Some participant information will be published, such as data of outcome measures results, but personal information of the participants will not be published.

When the data will become available and for how long

starting 1 year after publication

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

They must state the reasons for requesting information. They are not allowed to print the results.

From where data/document is obtainable

Applicants can email this address:
Motavalian.1993@gmail.com

What processes are involved for a request to access data/document

After reviewing the reasons for the data request, the information will be sent within a maximum of three weeks.

Comments

