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 myafascial 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
Street address
Ghods Ave , Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
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
Street address
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
Street address
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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Department of Physiotherapy,School of rehabilitation,Pitch-e shemirn, Enghelab avenue

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Person responsible for scientific inquiries

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Assistant professor, PHD, PT

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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