Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of Low Level Laser Therapy for treatment of cervical pain in patients with trigger points of upper trapezius

Protocol summary

Study aim
To determine the effectiveness of low level laser therapy for treatment of cervical pain in patients with trigger point of upper trapezius muscle.

Design
Single Blind , parallel , Randomized Controlled Trial

Settings and conduct
This Randomized Controlled Trial ,Double Blind ,Parallel study will be conducted at University of Lahore Teaching Hospital

Participants/Inclusion and exclusion criteria
Inclusion : Patients diagnosed with active upper trapezius trigger point. •Both Male and female •Age ranges from 18 to 55 Exclusion : Participants having contraindications for LASER e.g. Pregnancy, Tumors, Implants, Pacemaker, •Past History of fracture of shoulder joint or cervical spine •Whiplash injury •Comorbid medical diagnosis e.g. osteoarthritis •Psychiatric illness (e.g., schizophrenia or substance abuse) •Irritable skin around the area of treatment

Intervention groups
Patients of group-A will receive conventional physical therapy along with low level laser therapy (LLLT with Omega Class IIIB Laser therapy unit with pen probe.) While patients of group B, will receive conventional physical therapy only.

Main outcome variables
Neck pain , Neck Range of Motion and Neck Disability Indexes

General information

Reason for update

Acronym
Cervical pain Trigger points Upper trapezius Neck Pain Neck Range of Motion Neck Disability Index Low Level Laser Therapy

IRCT registration information
IRCT registration number: **IRCT20210409050912N1**
Registration date: **2021-08-29, 1400/06/07**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-29, 1400/06/07**
Update count: **0**

Registration date
2021-08-29, 1400/06/07

Registrant information

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Name of organization / entity
Faisal Institute of Health Sciences

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Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-28, 1400/05/06

Expected recruitment end date
2021-12-25, 1400/10/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of Low Level Laser Therapy for treatment of cervical pain in patients with trigger points of upper trapezius

Public title

Low Level Laser Therapy for treatment of cervical pain in patients with trigger points of upper trapezius

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed patients with active upper trapezius trigger point Age range from 18-55 years Male and Females

Exclusion criteria:

Participants having contraindications for LASER e.g. Pregnancy, Tumors, Implants, Pacemaker, Irritable skin around the area of treatment Past History of fracture of shoulder joint or cervical spine Whiplash injury Comorbid medical diagnosis e.g. osteoarthritis Psychiatric illness (e.g., schizophrenia or substance abuse). Psychiatric illness (e.g., schizophrenia or substance abuse).

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly allocated by use of computer-generated randomization sheet into two groups One for Group A and other for B. 2 Sets of 27 Unique Numbers per Set Range: From 1 to 54

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome assessor will be blind and will assess the subjects for inclusion criteria and will make assessment at the baseline ,then after 2 weeks and than after 4 weeks . Then outcome assessor will give all the recorded data to the principal investigator

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The University of Lahore

Street address

Lahore

City

Lahore

Postal code

38000

Approval date

2020-03-07, 1398/12/17

Ethics committee reference number

IRB-UOL-FAHS/718-IX/2020

Health conditions studied

1

Description of health condition studied

Upper Trapezius Trigger Points

ICD-10 code

Y93

ICD-10 code description

Trigger Points , Neck pain, neck ROM , Neck Functioning

Primary outcomes

1

Description

Neck pain

Timepoint

It will be assessed three times ,First at Baseline , Second after 02 weeks of treatment and third and last at the end of 04 weeks of treatment .

Method of measurement

Numeric Pain Rating Score- The numerical pain rating scale is considered as one of the best method available for the estimation of the intensity of pain. The NPRS is a categorical scale which provides a continuous scale for magnitude estimation of pain. NPRS consists of 11 points, which range from 0-10.0=no pain, 1-4=mild pain, 4-7=moderate pain 7-10=severe pain.

Secondary outcomes

1

Description

Neck Range of Motion.

Timepoint

First it will be assessed three times at Baseline , then after 02 weeks and at the end of 04 weeks of treatment .

Method of measurement

Universal Goniometer will used for measurement of Range of Motions of neck in all sides .

2

Description

Neck disability Index

Timepoint

First it will be assessed three times at Baseline , then after 02 weeks and at the end of 04 weeks of treatment.

Method of measurement

Neck Disability Index- The Neck Disability Index (NDI) is a 10-item questionnaire that measures a patient's self-

reported neck pain related disability. It is a questionnaire which measures the functional ability of the patient. It is of subjective nature i.e. patient fills the questionnaire himself by ranking his ability to do some specific task. It includes assessment of 10 tasks including personal care, pain, reading, headaches, lifting, concentration, driving, work, sleeping and recreation. Patient ranks questions according to the limitations he faces in ADLs and IADLs. NDI is most commonly used questionnaire for neck pain.

Intervention groups

1

Description
Experimental Group (Intervention group: One group will receive low-level laser therapy. Patient position: Patient comfortably will be seated on chair with arm rest and avoided unnecessary stretching of neck and shoulder muscles. Both physiotherapist and patient will wear protective googles. After identification of trigger point, trigger point will be marked with erasable marker than the treatment will be provided by the following parameters: Wavelength 820nm, Power 200mW, Pulse Rate 2.5Hz Energy Transferring 24 Jcm-2 for 15 sec and with pen probe.

Category
Rehabilitation

2

Description
Control group: Control group: Standard Chartered Society of Physiotherapy recommendations for neck pain will be followed. Moving head downwards to tuck in your chin on your chest and maintain this position for 5 seconds. Moving head backward and upward by pushing your chin forward so that throat is stretched and maintain this position for five seconds. All this protocol will be followed.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
The University of Lahore

Full name of responsible person
Arooj Munawar

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Sponsors / Funding sources

1

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Name of organization / entity
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https://www.google.com/search?q=uol+teaching+hospital+contact+number&sxsrf=ALeKk02kuGDj2M11wCeoYBIBSYSQ92a7hw%3A1627283972447&ei=BGL-YPrkGsPKgQbr5q7oDA&oq=uol+teaching+hospital&gs_lcp=Cgdnd3Mtd2l6EAEYADIHCAAQRxCwAzIHCAAQRxCwAzIHCAAQRxCwAzIHCAAQRxCwAzIHCAAQRxCwAzIHCAAQRxCwAzIHCAAQRxCwAzIHCAAQsAMQQzIHCC4QsAMQQ0oECEEYAFAAWABgsyhoAXACeACAAbUCiAG1ApIBAzMtMZgBAKoBB2d3cy13aXrIAQrAAQE&sclient=gws-wiz

Grant name
NA

Grant code / Reference number
Only

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
The University of Lahore

Proportion provided by this source
10

Public or private sector
Private

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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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The data document will be available on demand if any of the researcher want to use like data evaluation Performa and outcome assessment sheets.
When the data will become available and for how long
The data will be available after compilation and statistical analysis of the study.
To whom data/document is available
Researchers
Under which criteria data/document could be used

For sake of help and research promotion .

From where data/document is obtainable

from principal Investigator

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

The email is provided for this purpose .

Comments

This trial is purely based for study purpose .It has not involved any third party and any funding except educational support from the relative institute .