Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative Effects of Low-Level Laser Acupuncture and Dry Needling on Clinical and Functional Outcomes in Patients with Chronic Cervical Myofascial Pain Syndrome

Protocol summary

Study aim

To compare the effects of Low Level Laser Acupuncture with Dry Needling when using Routine Physical Therapy as an adjunct therapy to them for managing pain intensity, functional disability, Range of Motion and quality of life in Chronic Cervical Myofascial Pain Syndrome.

Design

Single Blind Randomized Controlled Trial with a parallel group design of 80 patients will have random allocation by Sealed Envelope Method.

Settings and conduct

Patients from the Physical Therapy Department of Rawal Hospital, Islamabad. The outcome Assessor will be kept blind during the whole trial regarding the treatment groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age group between 25- 50 years, Both male and female patients, Newly diagnosed cases of chronic Myofascial Pain Syndrome of Cervical Spine. Exclusion criteria: Patients receiving treatment by other methods like vapocoolants, subdural steroid injections etc, Cervical spine surgery within the past year, Fibromyalgia, Clinical evidence of any tumor or any space occupying lesion, Any co-morbid diseases

Intervention groups

Patients will be randomly assigned to a treatment group by Sealed Envelope Method, either Group-A (Low-Level Laser Acupuncture-830nm, 100 Mv/Cm2 and Routine Physical Therapy) or Group-B (Dry Needling and Routine Physical Therapy).The treatment procedures for both groups will be repeated for 3 sessions per week for 6 weeks (18 sessions) and a follow up consultation over a maximum period of Four weeks. The readings will be taken for three times (Pre-Treatment, Mid- Treatment and Post-Treatment) during the whole session.

Main outcome variables

Numeric Pain Rating Scale for Pain Intensity, Neck Disability Index for Functional Disability, Goniometer for Cervical Range of Motion and SF-36 Questionnaire for Quality of Life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043930N2**
Registration date: **2023-11-13, 1402/08/22**
Registration timing: **prospective**

Last update: **2023-11-13, 1402/08/22**
Update count: **0**

Registration date

2023-11-13, 1402/08/22

Registrant information

Name
Faryal Zaidi
Name of organization / entity
The University of Lahore
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Pakistan
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-25, 1402/09/04

Expected recruitment end date

2024-03-30, 1403/01/11

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative Effects of Low-Level Laser Acupuncture and Dry Needling on Clinical and Functional Outcomes in Patients with Chronic Cervical Myofascial Pain Syndrome

Public title
Chronic Cervical Myofascial Pain Syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Newly diagnosed cases of chronic MyofasciaL Pain Syndrome of Cervical Spine, Patients with at least moderate score (21% - 40%) in Neck Disability Index, Patients with at least >3 points on Numeric Pain Rating Scale, Decreased Cervical Range of Motion up to sixty percent. Bilateral/Unilateral neck pain and Myofascial Trigger Points in upper trapezius, levator scapulae or scalene muscles for at least three months, Taught muscle band and positive Jump Sign on putting finger pressure on the trigger point.
Exclusion criteria:
Patients receiving treatment by other methods like vapocoolants, subdural steroid injections etc. Cervical spine surgery within the past year Spondylolisthesis and Ankylosing spondylitis Vascular, neurological or rheumatic disorders Clinical evidence of any myelopathy or joint disorders Recent fracture of the cervical spine Cauda equina syndrome Osteoporosis Fibromyalgia Clinical evidence of any tumor or any space occupying lesion. Any co-morbid diseases
Age
From **25 years** old to **50 years** old
Gender
Both

Phase
2
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Random Allocation Software version 2 will be used for Block randomization design to allocate participants to the groups with an equal sample size over time. The groups will be labeled (E= experimental, C= control). Then a block size of four will chose.So, there will be six possible ways to equally assign participants to a block (EECC, ECEC, ECCE, CEEC, CECE, CCEE). Blocks will be randomly chosen to determine the assignment of all 80 individuals (40 participants in each group). Allocation concealment will be performed using sealed, opaque envelopes.
Blinding (investigator's opinion)
Single blinded
Blinding description
The treatment procedures will be repeated for 3 sessions per week for 6 weeks (18 sessions). The Pre-test, Mid-test & Post-test scores of Numeric Pain Rating Scale, Neck Disability Index, Goniometer and SF-36 Questionnaire will be collected and analysed by an outcome Assessor, who will be kept blind throughout the session in order to reduce any biasing in the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Board of Advanced Studies and Research, The University of Lahore
Street address
1-km Defence Road, Off Bhobatian Chowk
City
Lahore
Postal code
54590
Approval date
2023-06-19, 1402/03/29
Ethics committee reference number
REC-UOL-443-06-2023

Health conditions studied

1

Description of health condition studied
Myofascial pain syndrome is a frequently encountered musculoskeletal problem characterized by a hypersensitive trigger point. Symptoms of myofascial pain syndrome include pain and increased pain threshold, muscle spasms, and range of motion (ROM) limitation. The symptoms affect quality of life, decrease productivity, reduce work time, and increase the medical expenses borne by the patient. Myofascial pain syndrome frequently occurs in the upper body, with 84% of the trigger points found in the trapezius, scalene, levator scapulae, and infraspinatus muscles. The trapezius muscle is the most frequent site, being involved in 34% of cases. The development of myofascial pain syndrome is related to excessive repetitive activity. Activities that cause muscle tension and fatigue, poor posture, and poor ergonomic work environment are likely to be involved.

ICD-10 code
M79.12
ICD-10 code description
Myalgia of Auxiliary muscles, head and neck

Primary outcomes

1

Description
Pain Intensity
Timepoint
At the start of treatment and then after 9th and 18th treatment session.
Method of measurement
Numeric Pain Rating Scale

2

Description
Functional disability
Timepoint
At the start of treatment and then after 9th and 18th treatment session.
Method of measurement
Neck Disability Index

3

Description
Cervical Range of Motion
Timepoint
At the start of treatment and then after 9th and 18th treatment session.
Method of measurement
Goniometer

4

Description
Quality of Life
Timepoint
At the start of treatment and then after 9th and 18th treatment session.
Method of measurement
SF-36 Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Participants treated by Low-Level Laser acupuncture will be given goggles for eye protection. The trigger points on the Scalene, Levator scapulae and Trapezius muscles will be marked with an 'X' mark. The laser probe (01 cm in diameter) with the power output of 100mv/cm2, the frequency of 9.12 hz that emits a laser beam with 830 nm will be applied directly and perpendicularly into the skin. The irradiation dosage will be 5J/cm2 at each trigger point for Six minutes. The stretching of the Cervical ROM will be done at the end of a session.
Category
Treatment - Other

2

Description
Control group: In Dry needling group, while the patient is in prone position, the therapist will wear the surgical gloves, sterilize the area with alcohol pad and use pincer palpation to identify the trigger points. A 25G acupuncture needle (0.3* 30 mm) will be placed on the trigger point to a depth of 2cm. The insertion site will be monitored for local twitch responses (LTRs) for a maximum of 30 minutes with manipulation of the needle until no LTRs will be seen. The needles will be removed and any bleeding that occurre will be controlled. The stretching of the cervical ROM will be done at end of the session.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Rawal Hospital
Full name of responsible person
Dr. Muhammad Saad Hassan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Phone
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Email
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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
The University of Lahore
Proportion provided by this source
50
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
The University of Lahore
Full name of responsible person
Dr. Faryal Zaidi
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
Physiotherapy
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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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Consent form, Clinical Study Report, Statistical Plan files can be shared
When the data will become available and for how long
2 months after Publication
To whom data/document is available
People working in academic institutions or people

working in businesses can also apply to receive it

Under which criteria data/document could be used

Intervention Purpose

From where data/document is obtainable

faryal.pt@gmail.com

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

Full description about the purpose/aim of using the documents, Insight about the disorder and Intervention of the research

Comments