Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Effectiveness of Radial Extracorporeal Shockwave Therapy Versus High Intensity Laser Therapy in Patients With Myofascial Pain Syndrome of Upper Trapezius Muscle

Protocol summary

Study aim

To compare the pain intensity, neck range of motion, muscle length, neck disability, and frequency of pain symptoms between Radial Extracorporeal Shockwave Therapy and High-Intensity Laser Therapy in patients with Myofascial Pain Syndrome of the Upper Trapezius muscle.

Design

Randomised control trial with blind participants and outcome assessors

Settings and conduct

This study will be conducted in a laboratory setting, and a schedule will be established to allocate separate times for each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria -Aged between 18-24 years -Diagnosed with Myofascial pain syndrome of the Upper trapezius muscle -Duration of pain is equal to or more than 3 months -Severity of pain is equal to or more than 3 out of 10 Exclusion criteria -Use of medication -History of cancer -Wound in the area requiring treatment -Patient with a pacemaker -Pregnant -Diagnosed by a physician with a mental disorder -Vigorous exercise or physical activity -Experienced trauma in the neck area affecting the function

Intervention groups

This study will be divided into 3 groups. Participants in the Shockwave group will receive 2,000 shocks, consisting of 1,000 shocks at 1.5 bars with a frequency of 15 Hz at trigger points, and 1,000 shocks at 2 bars with a frequency of 8 Hz around the trigger point, with treatments conducted once a week. Participants in the High-intensity Power Laser group will be treated with lasers of wavelengths 810 nm and 980 nm, at a power of 7 watts, also once a week. Participants in the Control group, as well as those in all other groups, will perform stretching exercises daily and record data in a log book. The total duration of treatment for all groups is 4 weeks.

Main outcome variables

- Pain symptoms at the Upper trapezius muscle - Muscle length of the Upper trapezius muscle - Neck range of motion - Neck function - Frequency of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240207060929N1**
Registration date: **2024-02-26, 1402/12/07**
Registration timing: **prospective**

Last update: **2024-02-26, 1402/12/07**
Update count: **0**

Registration date

2024-02-26, 1402/12/07

Registrant information

Name
Kanruethai Threesittidath
Name of organization / entity
Walailak University
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+66 75 672 645
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-01, 1402/12/11

Expected recruitment end date

2024-06-30, 1403/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Radial Extracorporeal Shockwave Therapy Versus High Intensity Laser Therapy in Patients With Myofascial Pain Syndrome of Upper Trapezius Muscle

Public title

Comparison of the Effectiveness of Radial Extracorporeal Shockwave Therapy Versus High Intensity Laser Therapy in Patients With Myofascial Pain Syndrome of Upper Trapezius Muscle

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

A student aged between 18-24 years Diagnosed with Myofascial pain syndrome of the Upper trapezius muscle Duration of pain is equal to or more than 3 months Severity of pain during the day is equal to or more than 3 out of 10 (pain scale ≥ 3/10)

Exclusion criteria:

Use of medication such as anti-coagulants, pain relievers, and anti-inflammatories History of cancer Current infection or wound in the area requiring treatment Patient with a pacemaker History of easy bleeding Pregnant Diagnosed by a physician with a mental disorder such as depression Vigorous exercise or physical activity Experienced trauma in the neck area affecting the function of the upper trapezius muscle, such as wounds, fractures, or whiplash injuries Currently undergoing treatment for pain in the upper trapezius muscle area

Age

From **18 years** old to **24 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **69**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified Randomization with matched pairs of variables, including age, gender, and BMI. Subsequently, computer software is employed as the tool for randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

This study employs a double-blind method for both participants and outcome assessors. Once participants are randomized into groups, they are scheduled for treatment sessions at different times for each group. Furthermore, the outcome assessor, who is a physiotherapist unaware of the participant's group allocation, conducts baseline and post-treatment measurements. Another physiotherapist, who is responsible for overseeing the study, performs participant randomization into groups and administers the interventions.

Placebo

Used

Assignment

Parallel

Other design features

The sample size was determined using G*Power. The means and standard deviations were derived from a previous study, with the values being Mean±SD = 6.56 ± 2.06 and 6.46 ± 1.84, respectively. The calculated effect size was 0.46, resulting in a total of 58 participants, with an additional allowance for a 15% dropout rate. Consequently, the total number of participants in this study amounted to 69 (comprising 23 participants per group).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee in Human Research Walailak University

Street address

222 Thaiburi

City

Thasala

Postal code

80160

Approval date

2024-01-12, 1402/10/22

Ethics committee reference number

WUEC-24-016-01

Health conditions studied

1

Description of health condition studied

Myofascial pain syndrome at Upper trapezius muscle

ICD-10 code

M79

ICD-10 code description

Other and unspecified soft tissue disorders, not elsewhere classified

Primary outcomes

1

Description
Pain symptoms at upper trapezius muscle
Timepoint
Before intervention and 4 weeks after intervention
Method of measurement
Pain symptoms will be assessed using a Pressure Algometer, with participants indicating their level of pain on the Visual Analog Scale (VAS).

2

Description
Muscle length of the Upper trapezius muscle
Timepoint
Before intervention and 1, 2, 3, 4 weeks after intervention
Method of measurement
Muscle length will be measured using tape measurement, with assessment points located between the Spinous process of C7 and the Distal end of the acromion process. This measurement will be taken during neck flexion combined with lateral flexion to the opposite side and rotation to the same side.

3

Description
Range of motion of the neck
Timepoint
Before intervention and 1, 2, 3, 4 weeks after intervention
Method of measurement
Measurements will be conducted using a cervical range of motion device. The starting position will be seated in a chair. From this position, the degree of neck flexion, neck extension, lateral flexion of the neck, and neck rotation will be measured.

4

Description
Neck function
Timepoint
Before intervention and 1, 2, 3, 4 weeks after intervention
Method of measurement
The Neck Disability Index (NDI) comprises 10 questions covering the following areas: Pain Intensity, Personal Care, Lifting, Reading, Headaches, Concentration, Work, Driving, Sleep, and Recreation. Each question offers six choices, with scores ranging from 0 to 5. A score of 0 indicates no pain or interference with activity, while a score of 5 signifies very severe pain or extreme disruption, to the point of being unable to perform the activity. The total possible score for the NDI assessment ranges from 0 to 50 points.

5

Description
Frequency of pain
Timepoint
Before intervention and 1, 2, 3, 4 weeks after intervention
Method of measurement
A questionnaire will be utilized to investigate the frequency of pain.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Participants in the Shockwave group will receive 2,000 shocks, consisting of 1,000 shocks at 1.5 bars with a frequency of 15 Hz at trigger points, and 1,000 shocks at 2 bars with a frequency of 8 Hz around the trigger point, with treatments conducted once a week. The total duration of treatment for all groups is 4 weeks.
Category
Treatment - Devices

2

Description
Intervention group 2: Participants in the High-intensity Power Laser group will be treated with lasers of wavelengths 810 nm and 980 nm, at a power of 7 watts, also once a week. The total duration of treatment for all groups is 4 weeks.
Category
Treatment - Devices

3

Description
Control group: Participants in the Control group, as well as those in all other groups, will perform stretching exercises daily and record data in a log book. The total duration of treatment for all groups is 4 weeks.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Walailak university
Full name of responsible person
Kanruethai Threesittidath
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Sponsors / Funding sources

1

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School of Allied Health Science
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80160
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
No funding
Proportion provided by this source
100
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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kanruethai.si@wu.ac.th

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Data will be collected for the primary outcome measure only and all collected de-identified.

When the data will become available and for how long
Personal information of research project participants will be kept confidential and will not be publicly disclosed individually. A consolidated report will be generated, and all documents will be starting in March 2024 and securely destroyed by January 2028.

To whom data/document is available
The personal data of research participants will be collected on encrypted computers inaccessible to individuals not involved in the study. The researcher will anonymize information for academic purposes.

Under which criteria data/document could be used
The personal data of research participants will be collected on encrypted computers inaccessible to individuals not involved in the study. The researchers will analyze the results using the SPSS program, which is an offline application.

From where data/document is obtainable
Researchers will communicate with participants via telephone. Postal or email addresses, website URLs, and fax numbers are not required for this study. Data files will be treated as confidential and will not be disclosed publicly on an individual basis. A consolidated report will be produced, and all documents will be securely destroyed by January 2028.

What processes are involved for a request to access data/document
The data supporting the findings of this study are available from the corresponding author upon reasonable request. However, access will be provided only for the primary outcome measure and data that cannot be personally identified.

Comments