Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of High-intensity laser on pain, disability and upper trapezius muscle activity in women with cervical myofascial pain syndrome

Protocol summary

Study aim
Determine the effect of High-intensity laser on pain, disability and upper trapezius muscle activity in women with cervical myofascial pain syndrome

Design
Clinical trial includes two groups of intervention and control, one blinded on 40 patients, Randomization in the form of quadruple permutation blocks.

Settings and conduct
Patients will be entered into the clinical trial based on the inclusion criteria. They read and sign the informed consent form before starting the intervention, then the general information, pain and disability questionnaires will be completed. muscle activity will be recorded by surface electromyography device. Then the patients will be randomly assigned to one of two groups. this trial will be performed in the physiotherapy clinic, school of rehabilitation sciences, zahedan university of medical sciences.

Participants/Inclusion and exclusion criteria
Women,18 to 55 years old, neck pain, neck disability index 10 and 40, visual analogue scale 3 or greater, active trigger point in muscle; failure to complete sessions, exacerbation of symptoms or patient dissatisfaction with treatment

Intervention groups
Control group: conventional physiotherapy includes Trans cutaneous electrical nerve stimulation with frequency of 60 Hertz and pulse duration of 100 milliseconds for 20 minutes, ultrasonic waves with frequency of 1 Mega Hertz and continuous current for 5 minutes, Ischemic pressure 4 times, 90 seconds each time, which will be done by physiotherapist. Intervention group: In this group, in addition to the intervention of the control group (conventional physiotherapy) high-intensity laser with wavelengths of 660, 800, 905, 970 nano meter and maximum power of 20 watts will be applied by the physiotherapist for 5 minutes and 8 seconds.The intervention in both groups will be 12 sessions.

Main outcome variables
Pain; Disability; Upper trapezius muscle activity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220626055278N1**
Registration date: **2022-07-19, 1401/04/28**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-19, 1401/04/28**
Update count: **0**

Registration date
2022-07-19, 1401/04/28

Registrant information

Name
Hassan Namvar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 54 3344 6819

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hassan_753@zaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-05, 1401/04/14

Expected recruitment end date
2022-09-06, 1401/06/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of High-intensity laser on pain, disability and upper trapezius muscle activity in women with cervical myofascial pain syndrome

Public title

The Effect of high-intensity laser on pain and disability in women with neck pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

women aged 18 to 55 years Primary complaint of neck pain with shoulder girdle symptoms Percentage of neck disability index between 10 and 40 Visual analogue scale greater than or equal to 3 Existence of active trigger point in the upper trapezius muscle Having five major criteria and at least one of three minor criteria based on Simon diagnostic method for clinical diagnosis of myofacial neck pain syndrome Not having cervical spine surgery, canal stenosis at level of the cervical vertebrae, neck radicular pain, fibromyalgia

Exclusion criteria:

Failure to complete treatment sessions Exacerbation of symptoms or patient dissatisfaction with the continuation of treatment sessions

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done based on the quadruple permutation blocks method. All possible blocks are arranged as follows: 1:ABAB 2:AABB 3: ABBA 4: BBAA 5:BABA 6: BAAB We need 10 blocks to select 40 people. We randomly select these blocks from numbers 1 to 6. Using R soft ware, we choose a random number between numbers 1 to 6. For example, if number 6 is chosen as the first block and number 2 as the second block, the people who enter the study will be given BAABAABB respectively. Finally, group A: control and group B: intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will be unaware of the grouping.Physiotherapy modalities are explained to the patients and they are told that one or more modalities are used in their treatment, but they will be unaware of what modalities are used in each group.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Dr. Hesabi Square, Imam Hossein Blvd, compus of university of medical sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2022-06-25, 1401/04/04

Ethics committee reference number

IR.ZAUMS..REC.1401.109

Health conditions studied

1

Description of health condition studied

Myofascial pain syndrom

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain that is more than 3 or 3 befor intervention, decreases after the intervention.

Timepoint

Measurement befor the start of the intervention and 4 weeks after the application of the intervention

Method of measurement

Visual analoge Scale

2

Description

Disability, befor the intervention, its percentage is between 10 and 40 and decreases after the intervention.

Timepoint

Measurement befor the start of the intervention and 4

weeks after the application of the intervention

Method of measurement

Neck Disability Index Questionnaire

3

Description

Increased muscle activity that decreases after the intervention.

Timepoint

Measurement befor the start of the intervention and 4 weeks after the application of the intervention

Method of measurement

Surface Electromyography Device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: It will include high-intensity laser and conventional physiotherapy(trans cutaneous electrical nerve stimulation, ultrasonic waves and ischemic pressure). High-intensity laser with wavelengths of 660, 800, 905, 970 nano meter and maximum power of 20 watts is made in Italy. The time of laser treatment will be five minutes and eight seconds. The total energy received by the tissue is 2957 joules, which will be applied by the physiotherapist on the upper trapezius muscle of the patient in the prone position. In this group, trans cutaneous electrical nerve stimulation with frequency of 60 Hertz and pulse duration of 100 milliseconds and tolerable intensity of 10 to 30 milliamps for 20 minutes will be applied through two electrodes that we are placing on the upper trapezius muscle of the patient. Ultrasonic waves with frequency of 1 Mega Hertz and intensity of 1.5 watts per square centimeter and continuous current will be applied to the upper trapezius muscle for 5 minutes. Ischemic pressure will be applied 4 times, each time for 90 seconds with uniform pressure by the physiotherapist's thumb on the trigger points of the upper trapezius muscle. Trans cutaneous electrical nerve stimulation and ultrasonic waves will be performed by devices manufactured by Novin Medical Engineering company. The intervention will consist of twelve sessions, during four weeks, three times each week.

Category

Rehabilitation

2

Description

Control group: conventional physiotherapy will include trans cutaneous electrical nerve stimulation, ultrasonic waves and ischemic pressure. Trans cutaneous electrical nerve stimulation with frequency of 60 Hertz and pulse duration of 100 milliseconds and tolerable intensity of 10 to 30 milliamps for 20 minutes, will be applied through two electrodes that we are placing on the upper trapezius muscle of the patient. Ultrasonic waves with frequency of 1 Mega Hertz and intensity of 1.5 watts per square centimeter and continuous current will be applied to the upper trapezius muscle for 5 minutes. Ischemic pressure will be applied 4 times, each time for 90 seconds with uniform pressure by the physiotherapist's thumb on the trigger points of the upper trapezius muscle. Trans cutaneous electrical nerve stimulation and ultrasonic waves will be performed by devices manufactured by Novin Medical Engineering company. The intervention will consist of twelve sessions, during four weeks, three times each week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Razmjoomoghadam Physiotherapy Clinic

Full name of responsible person

Maryam Sargolzehi

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Ayatollah kafami St., Shahid Rajmjoomoghadam Comprehensive Center, Physiotherapy Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
Zahedan 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

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Person responsible for updating data

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