

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparative study of radial shockwave therapy and high intensity laser therapy in the treatment of patients with myofascial pain syndrome in neck and upper back area

Protocol summary

Study aim

Investigating and comparing the effects of radial shock wave therapy and high-power laser in the treatment of myofascial pain syndrome in the neck and upper back areas.

Design

A clinical trial without a control group, with parallel groups, one blinded, randomized, on 40 patients, random array subset selection (RASS) software and opaque sealed envelopes are used for randomization

Settings and conduct

The first group will receive radial shock wave therapy (ESWT: Extracorporeal shock wave therapy) in 3 sessions, 2 sessions per week with an intensity of 0.2 mj/mm², a frequency of 10 Hz, a number of 1000 impulses along with simple pain relief exercises. The second group, high intensity laser therapy (HILT) in 5 sessions, 3 sessions per week, with a total energy output of 1060 joules divided into three phases of 500, 60 and 500 joules, intensity of 50 J/cm² and average power: 3W (25) along with sports exercises and simple pain relief. Location: Kimia Physical Medicine and Rehabilitation Clinic, Tabriz

Participants/Inclusion and exclusion criteria

Entry requirements: Have at least two of the following criteria: 1. Acute or chronic pain in the neck and shoulder muscles 2. The presence of trigger points and tight bands in the muscles around the neck and head more than 2 points 3. The appearance of referred pain in the peripheral muscle in response to pressure on the trigger point. Non-entry conditions: The presence of clear radiculopathy, discopathy, severe cervical degenerative changes, history of surgery or trauma and systemic diseases and malignancies

Intervention groups

The first group will receive radial shock wave therapy (Extracorporeal shock wave therapy) along with simple

pain relief exercises. The second group, high intensity laser therapy along with sports exercises and simple pain relief

Main outcome variables

pain intensity: neck disability index: neck range of motion: pressure pain threshold

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003217N15**

Registration date: **2023-11-01, 1402/08/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-01, 1402/08/10**

Update count: **0**

Registration date

2023-11-01, 1402/08/10

Registrant information

Name

Fariba Eslamian

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of radial shockwave therapy and high intensity laser therapy in the treatment of patients with myofascial pain syndrome in neck and upper back area

Public title

Comparative study of radial shockwave therapy and high intensity laser therapy in the treatment of patients with myofascial pain syndrome in neck and upper back area

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Acute or chronic pain in the neck and shoulder muscles
The presence of trigger points and tight bands in the muscles around the neck and head more than 2 points
The appearance of referred pain in the peripheral muscle in response to pressure on the trigger point

Exclusion criteria:

The presence of clear radiculopathy based on the history and the presence of one of the findings of radiculopathy in the form of weakness, radicular pain, or decreased reflexes, or upper limb sensation disorder, and a positive Spurling test
The presence of extrude cervical discopathy proven in MRI
The presence of severe cervical degenerative changes and the presence of radiculopathy
History of cervical spine surgery or trauma
Existence of systemic diseases such as bleeding disorders or rheumatological and cardiovascular diseases
History of taking psychological drugs
Pregnancy
Malignancy

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Persons in a simple random way with random block method using 2 blocks and software random array subset selection (RASS) divided to two groups of shock wave and high power laser with a 1:1 allocation ratio using opaque sealed envelopes containing the numbers 1 and 2 in order to hide the process

Blinding (investigator's opinion)

Single blinded

Blinding description

The process of shock wave therapy and high-power laser is performed by a physiatrist and the assessment of patients before and after treatment is done by a resident of physical medicine and rehabilitation, who is unaware of the type of group

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

کمیته اخلاق دانشگاه علوم پزشکی تبریز

Street address

Daneshgah Ave, executive field of Tabriz University of Medical Sciences, Vice-Chancellor for research of Tabriz University of Medical Sciences, University Ethics Committee

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Approval date

2023-10-02, 1402/07/10

Ethics committee reference number

IR.TBZMED.REC.1402.483

Health conditions studied**1****Description of health condition studied**

Myofascial pain syndrome

ICD-10 code

R52.2

ICD-10 code description

Other chronic pain

Primary outcomes**1****Description**

Pain intensity

Timepoint

Before, immediately and 2 months after treatment

Method of measurement

Visual analogue scale (VAS)

2

Description

neck disability index (NDI)

Timepoint

Before, immediately and 2 months after treatment

Method of measurement

Neck disability Index questionnaire

3

Description

Neck range of motion(ROM)

Timepoint

bubble inclinometer

Method of measurement

Before, immediately and 2 months after treatment

4

Description

pressure pain threshold (PPT)

Timepoint

Before, immediately and 2 months after treatment

Method of measurement

Algometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group, radial shock wave therapy (ESWT: Extracorporeal shock wave therapy) in 3 sessions, 2 sessions per week with an intensity of 0.2 mj/mm², frequency of 10 Hz, number of 1000 impulses along with acetaminophen 500 mg and methocarbamol 500 mg every 12 hours for 10 days, upper trapezius stretching, isometric cervical paravertebral, posterior shoulder capsule stretching, and shrug exercises will be taught in three to ten sets during the treatment period of up to 6 weeks to be performed at home.

Category

Treatment - Devices

2

Description

Intervention group: The second group, high intensity laser therapy (HILT) in 5 sessions, 3 sessions per week, with a total energy output of 1060 joules divided into three phases of 500, 60 and 500 joules, intensity 50 J/cm² and average power: 3W along with acetaminophen 500 mg and methocarbamol 500 mg every 12 hours for 10 days and upper trapezius stretching exercises, isometric cervical paravertebral stretching, posterior shoulder capsule stretching and shrug exercise in three to ten sets during the treatment period They will be trained for up to 6 weeks to do at home

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Fariba Eslamiyan

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Department of physical medicine and rehabilitation,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Hiva Shadmani

Position

Resident of physical medicine and rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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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