

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effectiveness of dry needling versus low-level laser therapy in the treatment of myofascial trigger points of the upper trapezius muscles of patients referring to physical medicine clinics

Protocol summary

Study aim

Determining and comparing the therapeutic effects of dry needling and low-power laser in the treatment of trigger points in the upper trapezius muscle in clients of physical medicine clinics

Design

The following clinical trials were performed in three groups, including two intervention groups and one control group. There are 26 patients in each group. For patients, group A dry needling was performed. For group B patients, low-power laser was performed.

Settings and conduct

The present project is a standardized clinical trial study with parallel design (parallel controls) that was performed on 78 patients with myofascial upper trapezius muscle pain syndrome referred to the Physical Medicine Clinics of Isfahan University of Medical Sciences and annually. 1398 was implemented and followed up.

Participants/Inclusion and exclusion criteria

78 patients with neck and back pain entered the study by diagnosing the points of trigger of muscle fascia in the superior trapezius muscle who had referred to physical medicine clinics.

Intervention groups

All patients undergoing upper trapezius muscle stretching exercises will be placed 3 times a day (morning, evening and night) for 30 seconds each time for two weeks. Group C will only receive the same treatment. Group A Acupuncture Group B low power laser therapy

Main outcome variables

1. the Visual Analogue Scale (VAS): This is the 10 cm calibrated scale, with numbers ranging from zero (no pain) to 10 (the most severe possible pain). The criterion for scoring on this scale is the number on which the patient draws a line. 2. Neck Disability Index (NDI) Questionnaire Index contains 10 questions. There are 7

questions related to daily affairs, 2 questions related to pain and one question about concentration, 3. Shoulder Pain and Disability Index (SPDI) : There are two dimensions, one for pain and the other for functional activities.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200507047328N1**

Registration date: **2020-05-16, 1399/02/27**

Registration timing: **retrospective**

Last update: **2020-05-16, 1399/02/27**

Update count: **0**

Registration date

2020-05-16, 1399/02/27

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-20, 1397/12/29

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

2019-04-02, 1398/01/13

Actual recruitment end date

2020-03-16, 1398/12/26

Trial completion date

2020-03-18, 1398/12/28

Scientific title

The effectiveness of dry needling versus low-level laser therapy in the treatment of myofascial trigger points of the upper trapezius muscles of patients referring to physical medicine clinics

Public title

effect of dry needling versus low-level laser therapy in the treatment of myofascial trigger points

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patient with diagnosis of myofascial trigger point syndrom of upper trapezius muscle with base of Travel and Simons criteria age 18 or over VAS>5 Pain time over one month Patients tend to participate in the study

Exclusion criteria:

history of Fx in cervical vertebrae history of surgical operation in neck, known cervical myelopathy or radiculopathy history of psychologic or cognitive disorders opioid abuse and use of corticosteroid oral or IV active pregnancy coagulopathy

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **78**

Actual sample size reached: **78**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Due to the nature of the intervention and the lack of use of blinding platforms at the level of physician and patient, it cannot be performed. Only a person who performs statistical analysis can be kept blind from assigning groups

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of isfahan university of medical sciences

Street address

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Approval date

2020-01-20, 1398/10/30

Ethics committee reference number

IR.MUI.MED.REC.1398.564

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

myofascial trigger points syndrome

ICD-10 code

M79.62

ICD-10 code description

Pain in upper arm

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

Myofascial trigger point syndrome in the upper trapezius muscle with a VAS score above 5

Timepoint

Patients were evaluated in three periods before and immediately after the intervention and one month after the intervention

Method of measurement

Visual Analogue Scale, Index Neck Disability Index , and Shoulder Pain and Disability Index

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: acupuncture. For them, 4 dry needling sessions were performed on the trigger points two days apart. In trapezius muscle treated with dry needling, we mark the points of the muscle that have the most pain as trigger points. For dry needling, special thin

needles with a length of 25 mm and a thickness of 0.25 were used.

Category

Treatment - Other

2**Description**

Intervention group: low-power laser therapy. For them 3 sessions for two weeks, three days each time from the novin device, type LASER 860x, class I type BF 6 joules per square centimeter, average power of 100 MW for each point for 3 minutes done

Category

Treatment - Devices

3**Description**

Control group: stretching exercises .Control group: Stretching exercises. All patients - including this group - underwent upper trapezius muscle stretching exercises 3 times a day (morning, evening and night), each time for 30 seconds and for two weeks.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amin hospital

Full name of responsible person

Hamid Melali

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2**Recruitment center****Name of recruitment center**

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Mohammadreza Ansari

Position

resident

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