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 Indexcontains 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

Name

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Name of organization / entity

Country

Iran (Islamic Republic of)

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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 siences
Street address
ethics committee of isfahan university of medical sciences ,No 4 building, hezar jarib ave, isfahan city
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Isfehan
Postal code
8174673461
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
Esfahan 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
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