

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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

##### Name

mohammadreza ansari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3433 5337

##### Email address

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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**

ethics committee of isfahan university of medical sciences ,No 4 building, hezar jarib ave, isfahan city

**City**

isfahan

**Province**

Isfahan

**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

**Street address**

Eb-e-sina St, Amin hospital, isfahan city

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+98 31 3303 3400

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

Al-zahra hospital

**Full name of responsible person**

Majid Rezvani

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Al-zahra hospital ,Soffeh Ave, isfahan City

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjoy e javanmard

**Street address**

No. 6, 32nd Alley, Negarestan St, Kaveh Blvd, Isfahan City

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info@mui.ac.ir

**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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**Person responsible for scientific inquiries**

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**Name of organization / entity**

Esfahan University of Medical Sciences

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Saeid Khosrawi

**Position**

Professor

**Latest degree**

Specialist

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**Position**

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**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