

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Comparison of Effects of Dry needling and High Power Laser Therapy on Clinical Signs in Females with Upper Trapezoid Muscle Active Trigger Points (a Single-Blind Randomized Clinical Trial)

#### Protocol summary

##### Study aim

Comparison of Effects of Dry Needling and High Power Laser on clinical sign in Females with Upper Trapezoid Muscle Active Trigger Points

##### Design

A randomized (using block randomization method), single blinded, clinical trial with two parallel group design and a sample size of 30 patients

##### Settings and conduct

The study is performed in rehabilitation faculty of Iran University of Medical Sciences. Then eligible participants sign informed consent form and are randomly assigned to two groups of dry needling and high power laser by blocking. Treatment and assessment is done by separate persons and assessor and analyzer of data will be kept blind. The assessor is present only at the time of assessment (before and after treatment).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-35 years old; 30 < pain score < 60 mm based on visual analogue scale; presence of maximum of 3 active trigger points in upper trapezius muscle; history of trigger point pain > 3 months in trapezius muscle  
Non inclusion criteria: history of surgery; fractures and traumatic injuries to cervical spine; History of neurological; rheumatic and cognitive disorders; presence of symptoms of radiculopathy; malignancy; pregnancy

##### Intervention groups

Intervention group 1: participants received dry needle, passive stretch of upper trapezius muscle and postural correction education. Intervention group 2: participants received high-power laser, passive stretch of upper trapezius muscle and postural correction education.

##### Main outcome variables

Pain; pain pressure threshold; cervical lateral flexion and rotation to both; neck disability index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191208045652N2**

Registration date: **2020-03-27, 1399/01/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-27, 1399/01/08**

Update count: **0**

##### Registration date

2020-03-27, 1399/01/08

##### Registrant information

##### Name

marzieh Yassin

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 8052

##### Email address

m.yassin.pt@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-06-21, 1399/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Comparison of Effects of Dry needling and High Power Laser Therapy on Clinical Signs in Females with Upper Trapezoid Muscle Active Trigger Points (a Single-Blind Randomized Clinical Trial)

**Public title**

Effect of Dry needling and High Power Laser Therapy in treatment of Trigger Points

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women with age range of 18-35 years The presence of pain score between 30-60 mm according to visual analogue scale during rest or movement The presence of maximum of three active trigger points in the upper trapezoid muscle The history of trigger point pain for more than three months The presence of taut band in the upper trapezoid muscle during the touch The presence of sensitive and painful points in the response to 25 N pressure The presence of referred pain pattern in the response to pressure Ability to reading and writing to Persian language

**Exclusion criteria:**

The history of any treatment for trigger points and steroid injections over the past 3 months The history of fibromyalgia syndrome The history of surgery and fractures in the neck The presence of symptoms of cervical disc disorders such as radiculopathy The presence of neurological diseases The history of malignancy Pregnancy Severe postural disorders such as scoliosis and kyphosis The presence of infection and skin ulcers The history of receiving anticoagulants Fear of Needle The presence of communication and cognitive impairment The history of trauma such as whiplash injuries Patient dissatisfaction to continuing treatment and assessment

**Age**

From **18 years** old to **35 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, a simple block random allocation method will be used. In order to balance the number of samples in each group, a blocking method with random sizes of 6 will be used and non-transparent envelopes will be used to hide the random assignment. It should be noted that steps are taken to create a randomization sequence by a person who is not involved in any other stage of the research

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Assessment and treatment will be performed by two individuals. Assessor and analyzer the data are those who are unaware of the grouping and will be unaware of which group each subject belongs to. The assessor is present only at the time of assessment (before and after treatment).

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Iran university of medical sciences

**Street address**

Iran university of medical sciences, next to Milad tower, Hemmat highway

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۳۹۶۱۴۵۳۵

**Approval date**

2020-01-14, 1398/10/24

**Ethics committee reference number**

IR.IUMS.REC.1398.1044

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

Upper trapezius muscle active trigger point

**ICD-10 code**

M70.9

**ICD-10 code description**

Unspecified soft tissue disorder related to use, overuse and pressure

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

Pain

**Timepoint**

Pain before intervention, 2 days and 2 months after intervention

**Method of measurement**

pain with visual analogue scale

## Secondary outcomes

### 1

#### Description

Pain pressure threshold

#### Timepoint

Before intervention, 2 days and 2 months after intervention

#### Method of measurement

Algometer J-Tech, USA

### 2

#### Description

Side bending & rotation range of motion

#### Timepoint

Before intervention, 2 days and 2 months after intervention

#### Method of measurement

iPhone 8 application, goniometer

### 3

#### Description

Neck Disability Index

#### Timepoint

Before intervention, 2 days and 2 months after intervention

#### Method of measurement

Persian version of Neck Disability Index questionnaire

## Intervention groups

### 1

#### Description

Intervention group 1: dry needling (Dang bang South Korea, 50\*0.3 mm) with passive stretching and posture correction education based on pamphlet during 5 sessions, 2 times a week, for 3 weeks.

#### Category

Rehabilitation

### 2

#### Description

Intervention group 2: High power laser (New Age, Italy) with wavelength of 1064 nm, power 14 W, frequency 100 Hz with passive stretching and posture correction education based on pamphlet during 5 sessions, 2 times a week, for 3 weeks.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

#### Name of recruitment center

Physiotherapy clinic of Rehabilitation Faculty of Iran University of Medical Sciences

#### Full name of responsible person

Marzieh Yassin

#### Street address

Faculty of Rehabilitation; Iran University of Medical Sciences; Madadkaran street, Shahid Shahnazari street, Madar square, Mirdamad boulevard

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۳۴۸۷ - ۱۵۴۵۹

#### Phone

+98 21 2222 7124

#### Email

rehab@iums.ac.ir

### 2

#### Recruitment center

#### Name of recruitment center

Golestan Dormitory of Iran University of Medical Sciences

#### Full name of responsible person

Marzieh Yassin

#### Street address

Golestan dormitory, Madadkaran street, Shahid Shahnazari street, Madar square, Mirdamad boulevard

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۳۴۸۷ - ۱۵۴۵۹

#### Phone

+98 21 2222 7124

#### Email

rehab@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Dr. Seyed Abbas Motevalian

#### Street address

Iran University of Medical Sciences, Milad tower, Hemmat highway

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۴۴۹۶۱۴۵۳۵

#### Phone

+98 21 8670 2503

**Email**

motevalian.a@iums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Azize Prandnia

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

Golestan Dormitory, Madadkaran street, Shahid Shahnazari street, Madar square, Mirdamad boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

1545913487

**Phone**

+098 21 2225 6434

**Email**

azize.parande@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Marzieh Yassin

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Physical therapy department, Rasoul Akram hospital, Niayesh street, Sattarkhan street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 2222 8052

**Email**

m.yassin.pt@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Marzieh Yassin

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Physical therapy department, Rasoul Akram hospital, Niayesh street, Sattarkhan street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 2222 8052

**Email**

Azize.parande@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Not applicable

**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

**Title and more details about the data/document**

All data can be shared after unidentified people

**When the data will become available and for how long**

starting accessibility 6 months after printing results

**To whom data/document is available**

The information is accessible to all researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

Use of data is only possible by mentioning the name and organizational affiliation of the correspond and co-author of the project and the published article.

**From where data/document is obtainable**

Connect to Azize Parandnia by email:

azize.parande@gmail.com

**What processes are involved for a request to access data/document**

If information is used in scientific and therapeutic activities, information is provided as soon as possible.

**Comments**