

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### Effect of Dry Needling Versus Shock Wave Therapy on Pain and Dysfunction Following Active Trigger Points in Upper Trapezius Muscle

#### Protocol summary

##### Study aim

The aim of this study was to compare the efficacy of two methods of Dry Needling and Shock Wave therapy on pain and dysfunction of active trigger points in the upper trapezius muscle

##### Design

Three arm parallel groups randomized clinical trial, single blinded, two-session treatment

##### Settings and conduct

48 patients with myofascial pain syndrome are admitted to the physiotherapy department of Nikan hospital after inclusion criteria. Using simple randomization, patients are divided into Shock wave, Shock wave Placebo and dry needling groups. All three groups receive two sessions of treatment per week.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: ages 18-35 years old; having trigger points active with a specified bundle in the upper trapezius muscle; pain above 3 and less than 7 on the VAS scale; pain one to three months; referral pain. Exclusion criteria: performing injections or other treatments for trigger points during the research period; having a previous history of infectious diseases such as fibromyalgia and myopathy; malignancy or patients susceptible to infection; presence of central and peripheral neurological disorders; use of anticoagulants; having vascular diseases; fear of needling; skin ulcers in the treatment area.

##### Intervention groups

Shock wave Group: Upper Trapezius Muscle Shock Therapy is performed with 1000 impulses, 700 pulses on the Taut band of the Trapezius muscle and 300 pulses around the Taut band. Shock wave Group Placebo: In this group, the shock wave setting is as same as Shock wave Group without any impulse to the muscle. Dry needling Group: After inserting the needle into the muscle and observing the first twitch of the needle, leave it in the muscle for 5 minutes.

##### Main outcome variables

Pain; pain pressure threshold; disability based on NDI scale; lateral neck flexion range of motion

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190514043588N1**

Registration date: **2019-12-29, 1398/10/08**

Registration timing: **retrospective**

Last update: **2019-12-29, 1398/10/08**

Update count: **0**

##### Registration date

2019-12-29, 1398/10/08

##### Registrant information

##### Name

Mehran Toghtamesh

##### Name of organization / entity

Medical University Tehran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7757 0616

##### Email address

mehrantoghtamesh@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2019-11-22, 1398/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Effect of Dry Needling Versus Shock Wave Therapy on Pain and Dysfunction Following Active Trigger Points in Upper Trapezius Muscle

**Public title**  
Comparison of the Effects of Needling and Shock Wave Therapy on Active Trigger Points

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age 18-35 Having active trigger points with a distinct bundle in the upper trapezius muscle Touch the Taut Band on the upper trapezius muscle fibers Pain above 3 and less than 7 on the VAS scale Pain for one to three months Having referral pain  
**Exclusion criteria:**  
Performing injections or other treatments for trigger points during the research period Having a previous history of infectious diseases such as fibromyalgia and myopathy Malignancy or patients susceptible to infection Presence of central and peripheral neurological disorders Use of anticoagulants Having vascular diseases Fear Of Needle Skin ulcers in the treatment area

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

**Gender**  
Male

**Phase**  
N/A

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: **48**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients were randomly divided into one of three groups under study using encoded pocket.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The participants are blind to the treatment.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

Faculty of Rehabilitation, Tehran University of Medical Sciences, Enghelab Ave, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1148965111

#### Approval date

2019-08-07, 1398/05/16

#### Ethics committee reference number

IR.TUMS.FNM.REC.1398.092

## Health conditions studied

### 1

#### Description of health condition studied

Myofascial pain syndrome

#### ICD-10 code

M79.1

#### ICD-10 code description

Myalgia

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

At baseline and immediately after the first session and after the second session

#### Method of measurement

Visual Analog Scale

### 2

#### Description

Pressure Pain Threshold

#### Timepoint

At baseline and immediately after the first session and after the second session

#### Method of measurement

Algometer

### 3

#### Description

Lateral bending Of Neck

#### Timepoint

At baseline and immediately after the first session and after the second session

#### Method of measurement

Goniometer

## 4

### **Description**

Disability

### **Timepoint**

Beginning and end of treatment

### **Method of measurement**

Neck Disability Index Questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Dry Needling : In this group, needle enters the upper trapezius muscle trigger point and stays in the muscle for 5 minutes. Two treatment sessions with a 48 hour interval during a week.

#### **Category**

Treatment - Other

### 2

#### **Description**

Shock Wave Therapy: In this group, shockwave with a power of 38 mj / mm<sup>2</sup> and frequency of 10 Hz is applied to the upper trapezius muscle with 1000 impulses and two sessions of therapy with 48 h intervals during the week.

#### **Category**

Treatment - Other

### 3

#### **Description**

Placebo Shock Wave Therapy: In this group, a shockwave with a power of 38 mj / mm<sup>2</sup> and a frequency of 10 Hz is applied to the upper trapezius muscle without any impulse and two treatment sessions with 48 h intervals during the week.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Nikan Hospital

##### **Full name of responsible person**

Mehran Toghtamesh

##### **Street address**

Department of Physiotherapy, Nikan Hospital, 22 Bahman Ave., Army Boulevard

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1694636517

##### **Phone**

+98 21 2912 1018

##### **Email**

mehrantoghtamesh@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Nikan hospital

##### **Full name of responsible person**

Dr. Mehdi Shiravi

##### **Street address**

Department of Physiotherapy, Nikan Hospital, 22 Bahman Ave., Army Boulevard

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

9435114679

##### **Phone**

+98 21 2912 1018

##### **Email**

mehrantoghtamesh@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Nikan hospital

#### **Proportion provided by this source**

100

#### **Public or private sector**

Private

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

empty

#### **Country of origin**

#### **Type of organization providing the funding**

Persons

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Mehran Toghtamesh

##### **Position**

Masters student

##### **Latest degree**

Bachelor

##### **Other areas of specialty/work**

Physiotherapy

##### **Street address**

Department of Physiotherapy, Nikan Hospital, 22  
Bahman Ave., Army Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

9435114679

**Phone**

+98 21 2912 1018

**Email**

mehrantoghtamesh@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mehran Toghtamesh

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

Department of Physiotherapy, Nikan Hospital, 22  
Bahman Ave., Army Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

9435114679

**Phone**

+98 21 2912 1018

**Email**

mehrantoghtamesh@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mehran Toghtamesh

**Position**

Masters Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

Department of Physiotherapy, Nikan Hospital, 22  
Bahman Ave., Army Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

9435114679

**Phone**

+98 21 2912 1018

**Email**

mehrantoghtamesh@yahoo.com

## 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