

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A clinical trail to compare the effects of shock wave and dry needling on clinical symptoms of upper trapezium trigger points

#### Protocol summary

##### Summary

This single center clinical trial will be done for comparing the effects of shock wave (SW) and dry needling (DN) on clinical symptoms of upper trapezium trigger points (MTrPs). In this study, 40 patient with active MTrPs of upper trapezius muscle and with no specific neck or shoulder pain are selected and divided randomly into two groups using Randomized Allocation Software. In one group DN and in other group SW will be used. The patients with myofascial pain syndrome in Trapezius muscle with pain intensity 30 - 60 in VAS scale for 3 months are included. If they have any other musculoskeletal problem or use any other intervention for their problem, they will be excluded. Evaluation of treatment effects will be performed using a visual analog scale (VAS), pressure pain threshold (PPT) and neck disability index questionnaire in patient with neck pain. In both groups these variables are measured before the first treatment session and before of the second, third and fourth treatment sessions and also seven days following the last treatment session. Patients in both groups will participate in four treatment sessions (With an interval of three days between each session) during two weeks. During treatment sessions and before each intervention, two variables (PPT, VAS) are measured by first examiner. The order of these measurements in each session is determined randomly. According to target group, treatment method is performed by second examiner. At the end of each session evaluation of patients is executed by first examiner again. In both groups, results of treatment methods will be reevaluated seven days following the last treatment session.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016110318760N3**

Registration date: **2016-12-16, 1395/09/26**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-12-16, 1395/09/26

##### Registrant information

###### Name

Fariba Ghaderi

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1333 4647

###### Email address

ghaderif@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-Chancellor for Research of Tabriz University of Medical Science

##### Expected recruitment start date

2017-01-04, 1395/10/15

##### Expected recruitment end date

2017-12-21, 1396/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A clinical trail to compare the effects of shock wave and dry needling on clinical symptoms of upper trapezium trigger points

## Public title

The comparison between the effects of shock wave and dry needling on trigger points

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: myofascial pain syndrome in Trapezius muscle; pain intensity 60 -30 in VAS scale for 3 months. Exclusion criteria: contraindication of ESWT or dry needling; Pregnancy; Previous injection in MTrPs; Having had previous surgery in the neck or upper limb; Using anticoagulant drugs; advance osteopathic or arthropathic disorders of the cervical spine or the shoulder; Having ulcer in therapy region; Using the anti-pain drugs in last 24 hours; Having specific postural dysfunction

## Age

From **20 years** old to **50 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Randomization with Randomized Allocation Software (RAS)

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Ethics committee of Tabriz University of Medical Sciences, Tabriz University of Medical Sciences, Daneshgah Ave., Tabriz

##### City

Tabriz

##### Postal code

#### Approval date

2016-10-10, 1395/07/19

#### Ethics committee reference number

IR.TBZMED.REC.1395.762

## Health conditions studied

### 1

#### Description of health condition studied

Myofascial Trigger Point Syndrome

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Pressure pain threshold (PPT)

#### Timepoint

Each treatment session and one week after the last session

#### Method of measurement

digital algometer

### 2

#### Description

Pain Intensity

#### Timepoint

Each treatment session and one week after the last session

#### Method of measurement

Visual Analogue Scale (VAS)

## Secondary outcomes

### 1

#### Description

Disability

#### Timepoint

Each treatment session and one week after the last session

#### Method of measurement

neck disability index questionnaire (NDI)

## Intervention groups

### 1

#### Description

Control group: Shock wave 0.025 mJ/mm<sup>2</sup>, 1000 shocks per session for 4 sessions, once a week. Shock wave is a method of treatment in which mechanical shocks are applied on tender or trigger points to break these points and release adhesions.

#### Category

Rehabilitation

### 2

#### Description

Intervention group: Dry needling is applied for upper trapezius trigger points for 4 sessions and each session runs once a week. Dry needling is a treatment method in

which fine needles are inserted into trigger points to release adhesions and there is no injection in this method.

**Category**

Treatment - Surgery

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

Rehabilitation Faculty of Tabriz University of Medical Sciences

**Full name of responsible person**

Fariba Ghaderi

**Street address**

Clinic of Rehabilitation Faculty, Tavanir ave., Tabriz

**City**

Tabriz

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

Vice Chancellor for Research (VCR) of Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Mohhamad Reza Rashidi

**Street address**

Vice Chancellor for Research (VCR) of Tabriz University of Medical Sciences, Daneshgah Ave, Tabriz

**City**

Tabriz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research (VCR) of Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Fariba Ghaderi

**Position**

PhD, Faculty member

**Other areas of specialty/work****Street address**

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**Web page address**

## **Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*