

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparison of shock-wave Therapy and Low level laser on treatment of the Myofascial Trigger Points of Trapezius Muscles: A Randomized single-blind Clinical Trial

#### Protocol summary

##### Study aim

The aim of this research is comparing the effect of shockwave therapy and low level laser on treatment of myofascial trigger points of trapezius muscles. This study is a single-blind clinical trial. Seventy two patients will refer to the Fattemeh physiotherapy clinic in Rafsanjan. Three interventions of this study are shockwave, low level laser and conventional therapy of physiotherapy.

##### Design

In this study 3 treatment group will done through parallel design and assesses during 1st, 10th sessions and one month later.

##### Settings and conduct

In this study assessor evaluates the patients refer to Fattemeh physiotherapy clinic and divided them into 3 equal groups randomly.

##### Participants/Inclusion and exclusion criteria

Inclusion: aged 20-60 years, one month following the onset of pain, pain of trigger points are exist only in trapezius muscles. Criteria for selection of samples is based on Travel and Simons physical examination. Exclusion: tumor, use of anticoagulation drug, very insufficiency of kidney, convulsion, radicular pain due to peripheral nerve diseases of the neck and leaving of study.

##### Intervention groups

First group will use shockwave therapy by shockwave set (made in Novin company of Iran, 360G, 0.08 milijoule, 1.5 pressure, 100 frequency, 1500 shock during 3 minutes on trigger points). Second Group will use Low level laser set (made in Metron of Australia, 8 joule intensity, 100 mw, 810 nm wave length during 3 minutes on trigger points). Third group (conventional physiotherapy) are includes trapezius stretch, during 5 minutes and ultrasound set (made in ITO Japan, 1 MH frequency, 1.5 watt, during 5 minutes) on trigger point.

##### Main outcome variables

Intensity of local pain, Stiff of band, Radicular pain, Range of neck motion

#### General information

##### Reason for update

##### Acronym

ندارد

##### IRCT registration information

IRCT registration number: **IRCT20100129003220N10**

Registration date: **2019-05-28, 1398/03/07**

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

Last update: **2019-05-28, 1398/03/07**

Update count: **0**

##### Registration date

2019-05-28, 1398/03/07

##### Registrant information

##### Name

Dadollah Shahimoridi

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 39 1822 0040

##### Email address

d\_shahimoridi@rums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-06, 1397/12/15

##### Expected recruitment end date

2020-01-05, 1398/10/15

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of shock-wave Therapy and Low level laser on treatment of the Myofascial Trigger Points of Trapezius Muscles: A Randomized single-blind Clinical Trial

**Public title**  
The effect of shock-wave and laser on treatment of the myofascial trigger points of trapezius muscles

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Aged 20-60 years one month following the onset of trigger points of trapezius muscles diagnosis of this points of pain based on travel and simons criteria  
**Exclusion criteria:**  
Exclusion are includes tumor Using of anti-coagulation drug serve insufficiency of kidney convulsion radicular pain due to pressure on cervical nerve using of steroids drug prior surgery fracture of cervical and back pregnancy leaving of study.

**Age**  
From **20 years** old to **60 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **72**

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

**Randomization description**  
Assessor evaluates the patients based on inclusion criteria, then he divides them to random permuted blocks methods in 3 equal groups and refer to therapist.

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

**Blinding description**  
In this study assessor is different from therapist. Assessor is not aware of treatment but therapist and patients are aware from methods of treatment.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
none

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The ettics of committe of Rafsanjan University of medical Sciences

##### Street address

Central organization of Rafsanjan University of Medical Sciences,education assistance, Emam Ali Blvd

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7717893591

#### Approval date

2019-03-03, 1397/12/12

#### Ethics committee reference number

IR.RUMS.REC.1397.239

## Health conditions studied

### 1

#### Description of health condition studied

Musculoskeletal disease

#### ICD-10 code

M62.9

#### ICD-10 code description

Disorder of muscle, unspecified

## Primary outcomes

### 1

#### Description

Intensity of local pain

#### Timepoint

1st, 10th sessions and one month later

#### Method of measurement

By Visual Analogue Scale (VAS)

### 2

#### Description

Stiff band

#### Timepoint

1st, 10th sessions and one month later

#### Method of measurement

Assessor palpates the area of local pain

### 3

#### Description

Radicular pain

#### Timepoint

1st, 10th sessions and one month later

#### Method of measurement

Assessor asks for the present or absence of radicular pain from patient.

#### 4

##### **Description**

Limitation of movement

##### **Timepoint**

1st, 10th sessions and one month later

##### **Method of measurement**

Assessor evaluates the present or absence of movements limitation of patients.

#### **Secondary outcomes**

empty

#### **Intervention groups**

##### 1

##### **Description**

Intervention group: First group will receive shock-wave therapy by shock-wave set, made in Iran, 360G model. 0.08 millijoule, 1500 shock during 3 minutes on trigger points.

##### **Category**

Rehabilitation

##### 2

##### **Description**

Intervention group: Second Group will receive Low level laser by low level laser set, made in Australia, 8 joule intensity, 100 mv, 810 nm for 3 minutes on trigger points.

##### **Category**

Rehabilitation

##### 3

##### **Description**

Intervention group: Third group (conventional physiotherapy) are includes stretch of trapezius muscles during 5 minutes and ultrasound set (made in ITO company of Japan, 7P model, 1 MH frequency, 1.5 watt intensity during 5 minutes) on myofascial trigger point.

##### **Category**

Rehabilitation

#### **Recruitment centers**

##### 1

##### **Recruitment center**

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

Fattemeh physiotherapy clinic

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

Dadollah Shahimoridi

###### **Street address**

Alley 17, Moalem street

###### **City**

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###### **Email**

d\_shahimoridi@rums.ac.ir

#### **Sponsors / Funding sources**

##### 1

##### **Sponsor**

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

Rafsanjan University of Medical Sciences

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

Hamid Hostad Ebrahimi

###### **Street address**

Education Assistance, Central Organization of Rafsanjan University of Medical Sciences, Emam Ali Blvd

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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**

Rafsanjan 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**

Rafsanjan University of Medical Sciences

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

Dadollah Shahimoridi

###### **Position**

Instructor/Academic member

###### **Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for updating data**

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**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Sharing plan**

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

The data of this study will publish in the medical journal  
and internet.

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

It is possible after one year.

**To whom data/document is available**

All medical and none medical researchers will access to  
data.

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

It can be used to increase science clinical application.

**From where data/document is obtainable**

Researchers refers to author, internet, medical journal  
and libraries.

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

It is accessible through the internet and medical journals  
by giving the keyword.

**Comments**