Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Fattemieh 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 Fattemieh 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)

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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 milijoule, 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
Fattemieh physiotherapy clinic
Full name of responsible person
Dadollah Shahimoridi
Street address
Alley 17, Moalem street
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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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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