

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of combination of extracorporeal shock wave therapy (ESWT) and muscle energy technique (MET) on active trigger point in upper trapezius muscle

Protocol summary

Study aim

the effectiveness of combination of extracorporeal shock wave therapy and muscle energy technique on active trigger points in upper trapezius muscle.

Design

54 participants will be divided in three groups, randomly. Randomization will be performed using sealed, filled envelopes describing the treatment groups. We prepare three envelopes, in each of which one of the three methods is written. Each participant will choose one of the envelopes and will be divided in each treatment group.

Settings and conduct

The patients with active upper trapezius trigger points in the physiotherapy clinic of school of Rehabilitation will evaluate and will be divided in three groups. Group A will receive only MET while group B will receive only ESWT and group C will receive combination of MET and ESWT. In the end of treatment sessions, evaluations will be done, again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Age between 18-40 years. - Presence of a palpable taut band in upper trapezius muscle. - Presence of a nodule in upper trapezius muscle. - Presence of 1 to 3 trigger points in one side. - Iron or calcium deficiency
Exclusion criteria: - Diagnosed fibromyalgia - Cervical radiculopathy - Facial neuralgia - Coagulation alteration - Cancer - History of cervical or shoulder surgery - History of deep vein thrombosis - History of myopathy - Aspirin intake during the last 3 days

Intervention groups

1. Group A- treatment with only MET . 2. Group B - treatment with only ESWT . 3. Group C - treatment with combination of MET and ESWT .

Main outcome variables

• Visual analog scale VAS. • pain pressure threshold • neck range of motion • Neck disability index (NDI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130121012210N8**

Registration date: **2021-03-09, 1399/12/19**

Registration timing: **prospective**

Last update: **2021-03-09, 1399/12/19**

Update count: **0**

Registration date

2021-03-09, 1399/12/19

Registrant information

Name

Azadeh Shadmehr

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7752 8468

Email address

shadmehr@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combination of extracorporeal shock wave therapy (ESWT) and muscle energy technique (MET) on active trigger point in upper trapezius muscle

Public title

The effect of combination of shock wave therapy and muscle energy technique on neck pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18-40 years. Presence of a palpable taut band in upper trapezius muscle. Presence of a nodule in upper trapezius muscle. Presence of 1 to 3 trigger point in one side.

Exclusion criteria:

Diagnosed fibromyalgia Cervical radiculopathy Facial neuralgia History of cervical or shoulder surgery History of deep vein thrombosis History of myopathy

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will randomly assign into 3 groups of only MET , only ESWT and combination of MET and ESWT . Randomization will performed using sealed, randomly filled envelopes describing the treatment groups. We prepare three envelopes, in each of which one of the three methods is written.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not 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

school of Rehabilitation, Piche Shemiran, Enghelab street

City

Tehran

Province

Tehran

Postal code

1148965111

Approval date

2020-12-19, 1399/09/29

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.917

Health conditions studied

1

Description of health condition studied

Activetrigger points in upper trapezuis muscle

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

•Pain

Timepoint

before and after 1 week of intervention

Method of measurement

• visual analog scale

2

Description

Pain pressure threshold

Timepoint

before and after 1 week of intervention

Method of measurement

Algometer

3

Description

• Active neck range of motion

Timepoint

before and after 1 week of intervention

Method of measurement

Digital goniometer

4

Description

neck function

Timepoint

before and after 1 week of intervention

Method of measurement

neck disability index questionnaire (NDI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A- only Muscle energy techniques- in this group muscle energy technique will apply on the upper trapezius. First upper trapezius will put in stretch position and then its antagonist muscle is down 10 seconds isometric contraction.after 20 seconds relaxation,upper trapezius will be stretched again. This technique will do 3 times in 3 sessions.

Category

Rehabilitation

2

Description

Intervention group B: only shock wave- shock wave prob will put on active trigger points of the upper trapezius and mechanical stimulation with 2000 Bar pressure will apply for one minutes. his technique will do 3 times in 3 sessions.

Category

Rehabilitation

3

Description

Intervention group C: Combination of Muscle energy techniques and shock wave- Muscle energy technique will apply on the upper trapezius. First upper trapezius will put in stretch position and then its antagonist muscle is down 10 seconds isometric contraction.after 20 seconds relaxation,upper trapezius will be stretched again. Then shock wave prob will put on active trigger points of the upper trapezius and mechanical stimulation with 2000 Bar pressure will apply for one minutes.This technique will do 3 times in 3 sessions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation, Tehran University of Medical Sciences

Full name of responsible person

Azadeh Shadmehr

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ahmad Esmailzadeh

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International Campous, Qods Stree, Engelab street

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ic-research@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Sponsor: country of origin

Country of origin

IR

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Azadeh Shadmehr

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Tehran University of Medical Sciences

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more Data.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available