

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Effects of Dry Needling and Dry Needling Combined with Electrical Stimulation on Pain and Function in Patients with Subacute Musculoskeletal Neck Pain following Myofascial Trigger Points

Protocol summary

Study aim

The main object of this research is study comparing effects of dry needling combined with electrical stimulation versus dry needling alone on pain and function in patients with subacute neck pain following myofascial trigger points in upper quadrant muscles

Design

It will be a Double Blinded RCT. A total of 30 participants will be randomly divided into 2 groups i.e. treatment and control group. The total number of sessions will be 6 for 3 weeks with pre and post-treatment assessment.

Settings and conduct

Data will be collected from the Department of Rehabilitation Imam Hasan Hospital, Karbala, Iraq. The principal investigator will assign two therapists for this double-blinded RCT. After the screening and randomization, therapist number 1 will perform the pre-treatment assessment, the Therapist number 2 will treat the patients as per their group. After 6 sessions, therapist number 1 will again perform the post-treatment assessment. Therapist number 1 will be blinded to the treatment groups, while therapist number 2 will be blinded to the research hypothesis and objectives.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Both genders. Patients having subacute neck pain. Ages between 25-45 years. Neck pain between 30-70 on the visual analog scale score during activity and rest. Unilateral sub-acute trigger point from the past 22-84 days Exclusion Criteria: Patients having systemic disorders or migraine. Patients taking medication for pain in the previous 3 weeks prior to the study. The pregnant women. The patient having trauma in the neck during the past 6 months. The patients with skin inflammation and open wounds. Refuse to take part

Intervention groups

Group 1: Dry needling with a hot pack Group 2: Electrical

Dry needling with a hot pack

Main outcome variables

Visual Analog Scale Range of Motion of Cervical Spine
Functional Capacity Evaluation Neck Disability Index

General information

Reason for update

Acronym

MPS (Myofascial Pain Syndrome)

IRCT registration information

IRCT registration number: **IRCT20230604058379N1**

Registration date: **2023-07-05, 1402/04/14**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-05, 1402/04/14**

Update count: **0**

Registration date

2023-07-05, 1402/04/14

Registrant information

Name

ali Al Chlahawi

Name of organization / entity

Country

Iraq

Phone

+964 781 530 7009

Email address

nangy489@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2023-08-10, 1402/05/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Dry Needling and Dry Needling Combined with Electrical Stimulation on Pain and Function in Patients with Subacute Musculoskeletal Neck Pain following Myofascial Trigger Points

Public title

Effects of Dry Needling with Electrical Stimulation in The Treatment Subacute Neck Pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Both genders. The patients must have sub acute neck pain. The patients must have unilateral neck pain following the myofascial trigger point in the upper quadrant muscles. Age between 25-45 years. The patients must present unilateral sub-acute trigger point signs and symptoms from past 22 -84 days. The number of identified trigger points at the area must be between 5 – 10 and can be specified for all upper quadrant muscles.

Exclusion criteria:

The patients who had a systemic disorder or migraine
The patients were on medication for trigger points or physiotherapy treatment in previous 3 weeks prior to the study
The pregnant women. The patient had trauma in the neck area during the past 6 months
The patients with skin inflammation
The patients with the pen wounds
The patients who refused to continue the study for any reason
The patients who had needle phobia
The patients who had a bleeding disorder
The patients who had a cognitive disorder
The patients who had tumors or a background of malignancy disorders

AgeFrom **25 years** old to **45 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample sizeTarget sample size: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

We will use a simple lottery method for the random allocation of patients into the treatment and control groups. Equal size allocation will be done in this study. All the patients will be given a unique number after screening and then the numbers will be written on small papers of equal size. After that, all the papers will be put

in a box and shuffled. For the treatment group, one slip will be taken out by the patient and handed over to the therapist. The same procedure will be used for control group allocation. This sequence will be repeated till all the patients will be allocated into groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this open-label study, the physiotherapist was not blind to the groups. However, both the participants and the assessor would be blinded to the treatment protocols. The participants will also get verbal explanations of the study's purpose and the procedures that would be applied before any intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of the Faculty of Nursing and Midwifery and the Faculty of Rehabilitation - Tehran

Street address

School of Rehabilitation of Tehran University of MedicalSciences, Piche Shemiran, Enghelab Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417614411

Approval date

2023-05-13, 1402/02/23

Ethics committee reference number

IR.TUMS.FNM.REC.1402.025

Health conditions studied**1****Description of health condition studied**

Subacute Neck Pain for more than 3 weeks

ICD-10 code

M54.2

ICD-10 code description

Cervicalgia

Primary outcomes

1

Description

Visual Analog Scale for Pain

Timepoint

Before intervention and after 3 weeks.

Method of measurement

The therapist will ask the patient to report their pain using Visual Analog Scale.

2

Description

Range of Motion of Cervical Spine

Timepoint

Before intervention and after 3 weeks.

Method of measurement

The therapist will use Bubble Inclinator to measure the range of motion of the cervical spine.

3

Description

Functional Capacity Evaluation

Timepoint

Before intervention and after 3 weeks.

Method of measurement

The therapist will measure the score of functional capacity evaluation.

4

Description

Neck Disability Index

Timepoint

Before intervention and after 3 weeks.

Method of measurement

The therapist will measure the score of the Neck Disability Index.

Secondary outcomes

1

Description

Disability

Timepoint

Before treatment and after 3 weeks

Method of measurement

Neck Disability Index (NDI)

Intervention groups

1

Description

Intervention group: The participants will be randomly allocated into two groups: Group-1 The patients will be under the application of [Dry needling with hot pack] Group -2 The patients will be under the application of [Electrical Dry needling with hot pack] All participants were lying in prone position and did receive standard medical care including 7 minutes of superficial heat (hot

pack) before and after applying Dry needling. The period between hot pack and dry needling was about 3 min. Each protocol of intervention consists of 6 sessions for 3 weeks (2 sessions per week). The participants should not take any other treatment during research time. They must also follow the routine life without any extra activities such as sewing, typing, etc.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hasan hospital

Full name of responsible person

Dr hussein al hakeem

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotuhi

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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

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

empty

Country of origin

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

Ali hasan hadi

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

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Full name of responsible person

Ali hasan hadi

Position

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Latest degree

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Other areas of specialty/work

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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