Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 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 Chlaihawi

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
Age
From **25 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target 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 Inclinometer 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
Street address
street al hur
City
Karbala
Postal code
56001
Phone
+964 781 530 7009
Email
ah411970@gmail.com
Web page address
https://www.facebook.com/people/%D9%85%D8%B3%D8%AA%D8%B4%D9%81%D9%89-%D8%A7%D9%84%D8%A5%D9%85%D8%A7%D9%85-%D8%A7%D9%84%D8%AD%D8%B3%D9%86-%D8%A7%D9%84%D9%85%D8%AC%D8%AA%D8%A8%D9%89-%D8%B9%D9%84%D9%8A%D9%87-%D8%A7%D9%84%D8%B3%D9%84%D8%A7%D9%85-%D8%A7%D9%84%D8%AA%D8%B9%D9%84%D9%8A%D9%85%D9%8A/100057573514020/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotuhi
Street address
Tehran University of Medical Sciences, Qods Corner Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 81631
Email

tums_research@tums.ac.ir

Web page address

https://en.tums.ac.ir/en

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

Physiotherapy

Street address

Al atbaa

City

Karbala

Province

Karbala

Postal code

56001

Phone

+964 781 530 7009

Email

nangy489@gmail.com

Web page address

https://www.facebook.com/ptali.hassan.1

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Siamak Bashardoust Tajali

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Enqhelab squar , Tehran

City

Tehran

Province

Tehran

Postal code

0000

Phone

+98 912 107 9244

Email

s_bashardoust@yahoo.com

Web page address

Person responsible for updating data

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

Physiotherapy

Street address

Al atbaa

City

Karbala

Province

Karbala

Postal code

56001

Phone

+964 781 530 7009

Email

nangy489@gmail.com

Web page address

https://www.facebook.com/ptali.hassan.1

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