Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of adding Transfer Energy Capacitive and Resistive therapy (TECAR) to dry needling on pain, pressure pain threshold, functinal disability and neck range of motion (ROM) in people with active trigger points in upper trapezius muscle

Protocol summary

Study aim

To determine effects of adding tecar therapy to dry needling on pain intensity, pressure pain threshold, neck disability and active cervical range of motion in patients with active upper trapezius myofascial trigger points

Design

This study is a randomized, assessor-blinded clinical trial with two groups (control and intervention groups) using a parallel-group design, conducted on 44 patients

Settings and conduct

Eligible participants attending the Rehabilitation Faculty Clinic of Shahid Beheshti University of Medical Sciences will be randomly allocated to either the intervention or control group. The interventions will be delivered by the principal investigator in four sessions over two weeks. Outcome assessment, data collection, and statistical analysis will be performed by an independent assessor.

Participants/Inclusion and exclusion criteria

Participants will be adults aged 20–50 years with active myofascial trigger points in the upper trapezius muscle who have experienced pain with an intensity greater than 3 for more than 30 days. Individuals with a fear of needles, a history of cardiovascular disease, or a history of cervical surgery will be excluded from participation.

Intervention groups

In the control group, dry needling of the upper trapezius muscle is performed over 4 sessions (2 sessions per week). The intervention group receives, in addition to dry needling, 20 minutes of TECAR therapy (New Age, Italy), including 10 minutes of capacitive and 10 minutes of resistive therapy at an intensity of 20% to 50%. Pain intensity, cervical range of motion, pressure pain threshold, and functional disability are assessed at three time points: before the intervention, 48 hours after the last session, and 3 months after treatment.

Main outcome variables

Pain intensity, pressure pain threshold, functional disability, cervical active range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260703070055N1**
Registration date: **2026-08-28, 1405/06/06**
Registration timing: **prospective**

Last update: **2026-08-28, 1405/06/06**
Update count: **0**

Registration date

2026-08-28, 1405/06/06

Registrant information

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2027-01-21, 1405/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding Transfer Energy Capacitive and Resistive therapy (TECAR) to dry needling on pain, pressure pain threshold, functinal disability and neck range of motion (ROM) in people with active trigger points in upper trapezius muscle

Public title

The effect of adding Transfer Energy Capacitive and Resistive therapy (TECAR) to dry needling in upper trapezius active trigger points

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 and 50 years Pain intensity greater than 3 on the Numeric Pain Rating Scale (NPRS) for more than 30 days Presence of a palpable taut band and an active trigger point in the upper trapezius muscle, where stimulation of the trigger point reproduces or aggravates the patient's familiar pain. Negative findings on Upper Limb Tension Tests (ULTTs) No therapeutic intervention received within the previous 30 days Ability to understand and communicate in persian to complete the study questionnaires

Exclusion criteria:

History of surgery or fracture involving the neck and shoulder region within the past 2 years Presence of myelopathy, radiculopathy and rheumatologic diseases History of psychological or psychiatric disorders Pregnancy or breastfeeding Presence of infection, tumor and lymphedema Current use of corticosteroids or narcotic medications History of cardiovascular disease and the presence of a cardiac pacemaker Fear of needles and history of allergic reactions to needling procedures History of trauma or evidence of peripheral nerve involvement

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly allocated into two groups. Group 1 (control group) will receive dry needling alone, while group 2 (intervention group) will receive tecar therapy combined with dry needling. Randomization will be performed using the sealed opaque envelope method. Based on the total sample size of 44 participants, 44 opaque sealed envelopes will be prepared. Twenty-two envelopes will contain the allocation for Group 1 (dry needling) and the remaining twenty-two envelopes will contain the allocation for Group 2 (tecar therapy plus dry needling). After enrollment, each participant will be asked to randomly select one envelope, which will determine their treatment assignment.

Blinding (investigator's opinion)

Single blinded

Blinding description

The principal investigator is blinded to the participant selection and randomization process. However, the interventions for both the intervention and control groups are administered by the principal investigator. Participants are assessed at three time points: before the intervention, 48 hours after the final treatment session, and 4 weeks after the final treatment session (follow-up). All assessments are conducted by a physiotherapist who is blinded to the participants' group allocation. Thus, the outcome assessor remains blinded throughout the baseline, post-intervention, and follow-up assessments. Statistical analysis of the data will be performed after completion of data collection by the study's statistical consultant, who is also blinded to the participants' group allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committees of Vice Chancellor in Research Affairs Shahid Beheshti Medical University

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Shahid Beheshti University of Medical Sciences., Arabi Ave., Daneshjoo Blvd., Velenjak

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Approval date

2026-06-07, 1405/03/17

Ethics committee reference number

IR.SBMU.RETECH.REC.1405.144

Health conditions studied

1

Description of health condition studied
Active triggerpoints of upper trapezius
ICD-10 code
M54.2
ICD-10 code description
Cervicalgia

Primary outcomes

1

Description
Pain intensity
Timepoint
Baseline (before the intervention), 48 hours after the final intervention session, four weeks after the final intervention session
Method of measurement
Visual analogue scale

2

Description
Pressure Pain Threshold (PPT)
Timepoint
Baseline (before the intervention), 48 hours after the final intervention session, four weeks after the final intervention session
Method of measurement
Algometer

3

Description
Active neck range of motion
Timepoint
Baseline (before the intervention), 48 hours after the final intervention session, four weeks after the final intervention session
Method of measurement
goniometer

4

Description
Neck Functional Disability
Timepoint
Baseline (before the intervention), 48 hours after the final intervention session, four weeks after the final intervention session
Method of measurement
Neck Disability Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants will be positioned prone with their hands under the forehead for dry needling. After skin disinfection and wearing gloves, a 25 × 50 mm needle will be inserted into active trigger points of the upper trapezius muscle using the pincer palpation technique. The taut band will be grasped between the thumb and index finger and the needle will be advanced toward the trigger point to elicit a local twitch response. If no twitch response occurs, 2–3 needle movements will be performed, followed by static retention of the needle for 10 minutes. This procedure will be applied to all active trigger points and performed for four sessions (twice weekly, with a three-day interval) over two weeks. Following dry needling, calibrated New Age tecar therapy will be applied. Participants will remain in the prone position, with the passive electrode placed under the arm region. Active tecar therapy will be administered using a monopolar technique, including 10 minutes of capacitive mode followed by 10 minutes of resistive mode, using a 6 cm^2 electrode at an intensity of 20–50% according to the patient's comfortable thermal sensation. The active electrode will be applied over the upper trapezius muscle for a total of 20 minutes in each session. Tecar therapy will be performed for four sessions over two weeks following dry needling.
Category
Rehabilitation

2

Description
Control group: Participants will be positioned prone with their hands under the forehead for dry needling. After skin disinfection and using gloves, a 25 × 50 mm needle will be inserted into the active trigger points of the upper trapezius muscle using the pincer palpation technique. The taut band will be grasped between the thumb and index finger, and the needle will be advanced toward the trigger point to elicit a local twitch response. If no twitch response occurs, 2–3 needle movements will be performed, followed by static needle retention for 10 minutes. This procedure will be applied to all active trigger points and performed for four sessions (twice weekly, with a three-day interval) over two weeks. To control for the contact and placebo effects of tecar therapy, sham tecar will be applied after dry needling. The device will be activated for 20 seconds to produce a sensation of warmth, then switched off, and the electrode will be moved over the upper trapezius region for 20 minutes without active energy delivery.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Rehabilitation., Shahid Beheshti University

of Medical Sciences
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Sponsors / Funding sources

1

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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
Shahid Beheshti 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
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Ali Shirani
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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

All de-identified participant data will be made available to other researchers. Additional study documents, including data analyses and the study protocol, will also be published.

When the data will become available and for how long

Data access will begin in 2028.

To whom data/document is available

Researchers affiliated with academic institutions and medical students

Under which criteria data/document could be used

Other researchers, as well as healthcare professionals and rehabilitation therapists, will be able to use the data and findings for patient management and the development of future research projects.

From where data/document is obtainable

For further information or access requests, researchers may contact the study team via email at Alishirani1380127@gmail.com or visit the Rehabilitation Faculty of Shahid Beheshti University of Medical Sciences.

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

For further information or access requests, researchers may contact the study team via email at Alishirani1380127@gmail.com or visit the Rehabilitation Faculty of Shahid Beheshti University of Medical Sciences.

Comments