Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of neurodynamic techniques and Electroacupuncture on pain, grip strength and hand function in subject with carpal tunnel syndrome: Randomized control trial

Protocol summary

Study aim

The purpose of this study is to investigate the effect of the Neurodynamic technique with electroacupuncture on pain, strength, and hand function in people with carpal tunnel syndrome.

Design

A clinical trial, with a control group, with two parallel groups, double-blinded, randomized through blocking, was conducted on 38 people. The website https://www.randomizer.org/ will be used for randomization.

Settings and conduct

The study is performed in the rehabilitation faculty of Iran University of Medical Sciences. Then eligible participants sign an informed consent form and are randomly assigned to two groups of Electroacupuncture and placebo Electroacuouncture by Block-balanced randomization technique. Treatment and assessment are done by separate persons and the assessor and analyzer of data will be kept blind. The assessor is present only at the time of the assessment

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.18_60 year old. 2.Numbness and pain in the area of the median nerve (between 1 to 6 months). 3.Participants who have diminished nerve conduction values (<50 m/s), increased motor latency (>4 m/s), and increased sensory latency (> 3.5 m/s). 4.Positive phalen and tinel sign. Exclusion criteria: 1.Muscular atrophy. 2. Pregnancy. 3.Prior decompression surgery. 4.Post trauma to the wrist. 5.Diabetes Mellitus in case of taking insulin or suffering from diabetic neuropathy. 6.Cervical radiculopathy. 7.Any contraindication for needling such as local infection, bleeding tendency, or a history of needling shock. 8.Rheumatoid arthritis.

Intervention groups

Neurodynamic techniques along with electroacupuncture are used in the treatment group, and in the control group, neurodynamic techniques along with electroacupuncture are used as a placebo.

Main outcome variables

Pain, hand function, hand grip strength

General information

Reason for update

Correction following pilot study

Acronym

IRCT registration information

IRCT registration number: **IRCT20191208045652N5**
Registration date: **2022-12-07, 1401/09/16**
Registration timing: **prospective**

Last update: **2023-08-11, 1402/05/20**
Update count: **1**

Registration date

2022-12-07, 1401/09/16

Registrant information

Name

marzieh Yassin

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of neurodynamic techniques and Electroacupuncture on pain, grip strength and hand function in subject with carpal tunnel syndrome: Randomized control trial

Public title

The effect of electroacupuncture in carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18_60 year old Symptoms associated with carpal tunnel syndrome (pain and numbness) in at least 2 of the outer 3½ fingers for a period of one to six months Participants who have diminished nerve conduction values (<50 m/s), increased motor latency (>4 m/s), and increased sensory latency (> 3.5 m/s) Positive phalen and tinel sign

Exclusion criteria:

Thenar muscle atrophy Pregnancy Prior decompression surgery History of trauma in wrist and hand Metabolic problems (diabetes mellitus in case of insulin use or diabetic neuropathy) Cervical radiculopathy Any contraindication for needling such as local infection, bleeding tendency or a history of needling shock Rheumatoid diseases

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

After the completion of participant information and questionnaires, patients with carpal tunnel syndrome are randomly divided into two groups of treatment (group A) and control group (group B) with a ratio of one to one. Random allocation is done by variable blocks method, which will include four-letter blocks consisting of letters A and B. In each numbered envelope, one of the four-letter blocks containing two letters A and B is placed. Then, the treatment allocation list will be obtained at https://www.randomizer.org/.The letter A indicates electroacupuncture group and the letter B indicates non-real electroacupuncture. The random allocation process will be done by someone outside of the research team before the start of the study. After the initial evaluation of the patient by the examiner, numbered envelopes and stamps corresponding to the number of each person entered into the study will be given to him. Finally, after each patient enters the treatment sessions, the person providing the techniques will adjust the treatment interventions based on the letters inside the envelope. The examiners will be completely unaware of the letters inside the envelopes. Also, it should be noted that after placing the patients in the desired group, they are asked not to provide their grouping information to the examiner.

Blinding (investigator's opinion)

Double blinded

Blinding description

Evaluation and treatment will be done by two people. The person evaluating and analyzing the data are those who do not know about the grouping and will be unaware of which group each subject belongs to. The evaluator is present in the research only during the evaluation. The participants will not know which treatment group they have entered, in the treatment group, electroacupuncture along with neurodynamic techniques will be used, and in the control group, electroacupuncture placebo along with neurodynamic techniques will be used.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran university of medical sciences

Street address

Iran university of medical sciences, next to Milad tower, Hemmat highway

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Approval date

2022-09-18, 1401/06/27

Ethics committee reference number

IR.IUMS.REC.1401.533

Health conditions studied

1

Description of health condition studied
Carpal Tunnel Syndrome
ICD-10 code
G56.00
ICD-10 code description
Carpal tunnel syndrome, unspecified upper limb

Primary outcomes

1

Description
Functional status scale of Boston questionnaire
Timepoint
The first session before treatment, at the end of the 5th session, 48 hours after the 10th session, two months after the end of the treatment
Method of measurement
Persian Boston Questionnaire

2

Description
Symptom severity scale of Boston Questionnaire
Timepoint
The first session before treatment, at the end of the 5th session, 48 hours after the 10th session, two months after the end of the treatment
Method of measurement
Persian Boston Questionnaire

Secondary outcomes

1

Description
Pain
Timepoint
The first session before treatment, at the end of the 5th session, 48 hours after the 10th session, two months after the end of the treatment
Method of measurement
numeric pain rating scale

2

Description
Grip strength
Timepoint
The first session before treatment, at the end of the 5th session, 48 hours after the 10th session
Method of measurement
Hand dynamometer

Intervention groups

1

Description
Intervention group: Neurodynamic technique: arm adduction to 90, arm external rotation, wrist and fingers extension, forearm supination, and elbow extension. In this sequence, gliding and tension techniques will perform in the proximal and distal directions: (1) 1-direction proximal glide mobilization (movement_elbow extension_large amplitude of motion), (2) 1-direction distal glide mobilization (movement_wrist extension_large amplitude of motion), (3) 1-direction proximal tension mobilization (movement_elbow extension_small amplitude of motion at the end of the movement), and (4) 1-direction distal tension mobilization (movement_wrist extension_small amplitude of motion)In both groups, the standard protocol consisted of 3 series of 20 repetitions of glide and tension neurodynamic techniques separated by inter-series intervals of 15 seconds, twice a week for 10 sessions. Electroacupuncture: The following eight acupoints were applied: TW-5, PC-7, HT-3, PC-3, SI-4, LI-5, LI-10 and LU-5 on the affected side. After disinfecting the skin, therapist would insert sterile, 0.25x40 mm, into each acupoint with the aid of a guide tube. Punctures will make to a depth of 1–3 cm, depending on the thickness of the patient's wrist, hand and forearm. After insertion would perform bidirectional rotations of the needle sheath to achieve Deqi, indicating a patient-reported sensation of soreness, tingling, heaviness or distension at each acupoints. After insertion of all acupoints, electro-stimulation will apply immediately in the following combinations: TW-5 + PC-7, SI-4 + LI-5, LI-10 + LU-5, and HT-3 + PC-3, using the SDZ-II electroacupuncture instrument (2-4 Hz, continuous wave). The intensity should tolerable to the patient. The electro-simulation lasted for 20 minutes and then needles will remove, twice a week for 10 sessions.
Category
Rehabilitation

2

Description
Control group: Neurodynamic technique: arm adduction to 90, arm external rotation, wrist and fingers extension, forearm supination, and elbow extension. In this sequence, gliding and tension techniques will perform in the proximal and distal directions: (1) direction proximal glide mobilization (movement_elbow extension_large amplitude of motion), (2) direction distal glide mobilization (movement_wrist extension_large amplitude of motion), (3) direction proximal tension mobilization (movement_elbow extension_small amplitude of motion at the end of the movement), and (4) direction distal tension mobilization (movement_wrist extension_small amplitude of motion)In both groups, standard protocol consisted of 3 series of 20 repetitions of glide and tension neurodynamic techniques separated by inter-series intervals of 15 seconds, twice a week for 10 sessions. Sham electroacupuncture: After disinfecting the skin, sham EA on therapeutic acupoints plus no skin penetration plus no electrical stimulation. After 20

minutes needles will remove, twice a week for 10 sessions.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Physiotherapy clinic of Rehabilitation Faculty of Iran University of Medical Sciences

Full name of responsible person
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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
Iran 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
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Position
Student

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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