Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparative effect of tecar therapy versus phonophoresis on improvement of symptoms, function and electrodiagnostic and sonographic findings in patients with mild to moderate carpal tunnel syndrome

Protocol summary

Study aim
Determining and comparing the effect of tecar therapy and phonophoresis on the improvement of carpal tunnel syndrome

Design
The randomized, double-blind clinical trial, with the parallel groups, on 50 patients

Settings and conduct
In this randomized double-blind clinical trial study, 50 eligible patients referred to Amin Hospital in Isfahan will be included in the study and randomly divided into 2 groups. Patients in the first group will undergo Tecar therapy, and patients in the second group will undergo phonophoresis. The intervention will be performed in such a way that the patient, the investigator, and the data analyst will not have any knowledge of the type of intervention and the conditions will be double-blind. Patients' symptoms and function will then be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria include a mild to moderate carpal tunnel syndrome diagnosis by nerve and muscle strips and consent to participate in the study. Exclusion criteria include rheumatoid arthritis, diabetes, hypothyroidism, peripheral vascular disease, active cancer, cervical radiculopathy and polyneuropathy, pregnancy, a cardiac pacemaker, having a history of corticosteroid injection in the carpal tunnel area in the last quarter, and having a history of carpal tunnel syndrome surgery.

Intervention groups
Intervention group 1: Patients in this group will receive standard treatments. In addition, patients will receive Tecar therapy. Intervention group 2: Patients in this group will receive standard treatments. In addition, patients will be treated with phonophoresis.

Main outcome variables
Symptoms and function of the syndrome; Cross-sectional area (CSA) of the median nerve; Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220305054198N1**
Registration date: **2022-04-03, 1401/01/14**
Registration timing: **prospective**

Last update: **2022-04-03, 1401/01/14**
Update count: **0**

Registration date
2022-04-03, 1401/01/14

Registrant information

Name
Zahra Abbasian

Name of organization / entity

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Iran (Islamic Republic of)

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+98 31 3261 8907

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-04, 1401/01/15

Expected recruitment end date
2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effect of tecar therapy versus phonophoresis on improvement of symptoms, function and electrodiagnostic and sonographic findings in patients with mild to moderate carpal tunnel syndrome

Public title

Comparison oftecar therapy versus phonophoresis on improvement of symptoms of patients with mild and moderate carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of mild to moderate carpal tunnel syndrome by nerve and muscle tape Satisfaction to participate in the study

Exclusion criteria:

Rheumatoid arthritis, diabetes, hypothyroidism, peripheral vascular disease, active cancer, cervical radiculopathy and polyneuropathy Pregnancy Having a Heart Pacemaker Having a history of corticosteroid injection in the carpal tunnel area in the last quarter Having a history of carpal tunnel syndrome surgery

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 50 eligible patients are randomly selected. For this, the letter A is written on 25 sheets and the letter B is written on 25 sheets and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Given the type of intervention used in each of the two groups, the researcher is aware of the type of intervention in each group. But the patient, the investigator and the data analyser will not be aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfehan

Postal code

8179964167

Approval date

2022-01-23, 1400/11/03

Ethics committee reference number

IR.MUI.MED.REC.1400.767

Health conditions studied

1

Description of health condition studied

Carpal tunnel syndrome

ICD-10 code

G56.0

ICD-10 code description

Carpal tunnel syndrome

Primary outcomes

1

Description

Severity of symptoms

Timepoint

Before, immediately, one month and three months after the intervention

Method of measurement

Boston Questionnaire

2

Description

Function score

Timepoint

Before, immediately, one month and three months after the intervention

Method of measurement

Boston Questionnaire

3

Description
Cross-sectional area (CSA) of the median nerve
Timepoint
Before and three months after the intervention
Method of measurement
Sonography

4

Description
Pain
Timepoint
Before, immediately, one month and three months after the intervention
Method of measurement
Visual Analogue Scale

5

Description
Nerve Conduction Velocity (NCV) across wrist
Timepoint
Before and three months after the intervention
Method of measurement
Nerve and muscle strip

6

Description
Sensory nerve action potential (SNAP) latency from median nerves
Timepoint
Before and three months after the intervention
Method of measurement
Nerve and muscle strip

7

Description
Compound Muscle Action Potential (CMAP) Amplitude from median nerves
Timepoint
Before and three months after the intervention
Method of measurement
Nerve and muscle strip

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients in this group will receive standard treatments. In addition, patients will receive Tecar therapy(TECAR WINBACK made in France). In this way, the patient is sitting. The dorsal surface of the patient's hand will be placed on the insulating pad of the implant and the active pad on the patient's wrist will be placed on the volar surface. After rubbing the conductive cream on the volar surface of the wrist, using the capacitive model (CET) (frequency 500 kHz), in the path of the median nerve from the wrist to the palm for 15 minutes with an intensity of at least 20 and maximum 40, is moved. Eight sessions will be performed twice a week for patients.
Category
Treatment - Other

2

Description
Intervention group 2: Patients in this group will receive standard treatments. In addition, patients will be treated with phonophoresis. Following the use of the gel, the ultrasound probe will be placed perpendicular to the wrist. In each session, 15 minutes of pulse phonophoresis (1 to 4) with a frequency of 3 MHz and an intensity of one w/cm2 will be performed with hydrocortisone. Eight sessions of phonophoresis treatment will be performed twice a week.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Amin Hospital
Full name of responsible person
Saeid Khosrawi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Saeid Khosrawi
Position
Professor
Latest degree
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Person responsible for updating data

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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 further information

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