Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the efficacy of TECAR © on the improvement of clinical and neuroelectrophysiological symptoms in patients with mild to moderate carpal tunnel syndrome.

Protocol summary

Study aim

Determine the effectiveness of TECAR therapy on clinical and neuroelectrophysiological symptoms of patients with mild to moderate carpal tunnel syndrome.

Design

The present study is a blind clinical trial study with parallel, randomized groups that will be performed on 50 samples.

Settings and conduct

Patients with mild to moderate carpal tunnel syndrome who have will diagnosed in physical medicine clinics of Isfahan University of Medical Sciences will be referred to Amin Hospital for TECAR therapy. In the control group, patients will treat with TECAR off device. Both groups will also receive splints and vitamin B1 for four weeks.

Participants/Inclusion and exclusion criteria

A patient over 18 years of age with unilateral or bilateral idiopathic mild and moderate carpal tunnel syndrome confirmed by EMG-NCS and clinical examination and lasting more than one month will be referred. If the patient has a systemic disease such as diabetes, etc., or has a fracture of the hand and wrist, or has neuropathy, or vascular disease, or is pregnant, or has a pacemaker or prosthesis, he will not be included in the plan.

Intervention groups

In the intervention group, patients will have eight sessions of 15-minute TECAR therapy with a TECAR device in the patients' wrist area of the carpal tunnel. In the control group, TECAR device will be used off.

Main outcome variables

Treatment; Severity of symptoms; Functional status; Pain; SNAP latency; CMAP latency; SNAP amplitude; NCV across wrist; sex; Age; Tinnel test; Fallen test; Reverse phalen's test; Compression test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220405054422N1**
Registration date: **2022-04-30, 1401/02/10**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-30, 1401/02/10**
Update count: **0**

Registration date

2022-04-30, 1401/02/10

Registrant information

Name

Hamid reza Ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the efficacy of TECAR © on the improvement of clinical and neuroelectrophysiological symptoms in patients with mild to moderate carpal tunnel syndrome.

Public title
Evaluation of the effectiveness of TECAR therapy in carpal tunnel syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patient with unilateral or bilateral idiopathic mild and moderate carpal tunnel syndrome confirmed by EMG-NCS and clinical test and lasting more than one month.

Exclusion criteria:
Systemic and local diseases (diabetes, RA, wrist arthritis, hypothyroidism, etc.) Cancer Pregnancy Burns on the hands and forearms IUD, Pacemaker, prosthesis Peripheral vascular diseases Fractures in the wrist and hand area Corticosteroid injection in the last trimester in the carpal tunnel

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be done by double block randomization method. Thus, the first client with a diagnosis of CTS will be placed in a group (treatment or control) by lottery. Then the second person will be in the opposite group. The lottery will be held again by referring to the third person and will be placed in a group (trick or control). Then the fourth person will be in the opposite group. Thus, the last person will be in the treatment and control groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
The patient is not aware that the tecar is actively performed or the test is off.

Placebo
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
Hezar jerib Ave

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2021-07-27, 1400/05/05

Ethics committee reference number
IR.MUI.MED.REC.1400.340

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
Symptom severity scale

Timepoint
At the beginning of the study and 1 and 2 months after treatment

Method of measurement
Boston Carpal Tunnel Syndrome Questionnaire

2

Description
Functional status

Timepoint
At the beginning of the study and 1 and 2 months after treatment

Method of measurement
Boston Carpal Tunnel Syndrome Questionnaire

3

Description
Pain

Timepoint
At the beginning of the study and 1 and 2 months after treatment

Method of measurement

Visual Analogue Scale

4

Description
Median SNAP peak latency
Timepoint
At the beginning of the study and 2 months after treatment
Method of measurement
EMG machine

5

Description
Median motor onset latency
Timepoint
At the beginning of the study and 2 months after treatment
Method of measurement
EMG machine

6

Description
Median SNAP amplitude
Timepoint
At the beginning of the study and 2 months after treatment
Method of measurement
EMG machine

7

Description
Median sensory NCV across wrist
Timepoint
At the beginning of the study and 2 months after treatment
Method of measurement
EMG machine

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: TECAR therapy for 15 minute in 8 session + wrist splint (one month) + vitamin B 1 300 mg daily
Category
Treatment - Devices

2

Description
Control group: TECAR therapy (device off)for 15 minutes in 8 session + wrist splint (one month) + vitamin B 1 300 mg daily
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Amin hospital
Full name of responsible person
Hamid reza Ghasemi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Esfahan 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
Hamid reza Ghasemi
Position
Resident
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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
Collected data, data analysis and results
When the data will become available and for how long
Six months after the publication of the results
To whom data/document is available
Employees of scientific institutes and physicians
Under which criteria data/document could be used
To use the results for treatment or re-research
From where data/document is obtainable
Email the person in charge of the research project, Mr. Hamidreza Ghasemi dr.ghasemi85@gmail.com
What processes are involved for a request to access data/document
Information will be sent within a month after the call.
Comments