

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 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 (treatment 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

Isfahan

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

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?

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
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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