# 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)

**Phone**

+98 31 3668 0048

**Email address**

dr.ghasemi@resident.mui.ac.ir

**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
**Street address**
EBN E SINA street
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**Postal code**
8148653141
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dr.ghasemi85@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Mansour siavash
**Street address**
Hezar jerib Ave
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**Email**
siavash@med.mui.ac.ir
**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**
Medical doctor
**Other areas of specialty/work**
Physical Medicine
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## Person responsible for scientific inquiries

**Contact**
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Esfahan University of Medical Sciences
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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**