

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effectiveness of TECAR therapy and neurodynamic techniques VS. neurodynamic techniques and placebo TECAR on pain and function in subjects with carpal tunnel syndrome.

#### Protocol summary

##### Study aim

The effectiveness of TECAR therapy and neurodynamic techniques VS. neurodynamic techniques and placebo TECAR on pain and function in subjects with carpal tunnel syndrome.

##### Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment. The sample size is calculated based on a 95% confidence interval and a test power of 80%, based on a 15-person pilot on the study.

##### Settings and conduct

6 sessions of treatment in Iran university physiotherapy clinic

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with age range of 18-60 years that have the symptoms of CTS for 1-6 months. 2. Symptoms associated with the syndrome (pain and numbness) in at least 2 Fingers out of 3 and a half external fingers for more than a month and less than a year. 3. Diagnosis of mild to moderate carpal tunnel syndrome according to neurotransmission studies (terminal motor delay greater than 4 ms and sensory terminal delay greater than 3.5 ms) 4. Fallen and tunnel tests are positive. Exclusion criteria: 1. Pregnancy. 2. Tenar muscle atrophy. 3. History of any hand or wrist surgery. 4. Metabolic problems (diabetes mellitus, kidney disease, thyroid dysfunction); 5. Cervical radiculopathy. 6. Fibromyalgia and other musculoskeletal disorders. 7. Any history of severe injury to the wrist or wound in the wrist area. 8. Any job that is a risk factor for carpal tunnel syndrome, such as typists.

##### Intervention groups

Group 1: TECAR therapy with neurodynamic techniques.  
Group 2: placebo TECAR with neurodynamic techniques.

##### Main outcome variables

Grip strength; pain; functional status; symptom severity.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191208045652N3**

Registration date: **2021-03-18, 1399/12/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-03-18, 1399/12/28**

Update count: **0**

##### Registration date

2021-03-18, 1399/12/28

##### Registrant information

##### Name

marzieh Yassin

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 8052

##### Email address

m.yassin.pt@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-19, 1399/10/30

##### Expected recruitment end date

2021-08-20, 1400/05/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effectiveness of TECAR therapy and neurodynamic techniques VS. neurodynamic techniques and placebo TECAR on pain and function in subjects with carpal tunnel syndrome.

## Public title

Effect of TECAR therapy and neurodynamic techniques in treatment of carpal tunnel syndrome.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with age range of 18-60 years of Pain and paresthesia in at least 2 fingers of 3/5 lateral fingers for 1-6 months. Diagnosis of CTS based on EMG tests (distal motor latency >4m.s and distal sensory latency >5/3 m.s) Positive Phalen and Tinel test Ability to read and write in Persian

### Exclusion criteria:

pregnancy Thenar atrophy history of any hand or wrist surgery Metabolic diseases (Diabetes mellitus, thyroid or kidney problem) cervical radiculopathy Fibromyalgia or other musculoskeletal disorders Any history of severe trauma to the wrist and Connective tissue disorders Patient dissatisfaction with the continuation of the treatment and evaluation process

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this study, a simple randomization method is used. Randomization tool is also a software for random sequence production (software allocation Random). A set of random numbers is given by the software and before starting the study, it is determined that the intervention group of even numbers is assigned to the control group of odd numbers. Concealment Allocation is used for hiding, Which refers to the method used to execute a random sequence on study participants, in such a way that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed in random sequence in this method, each of the random sequences created is recorded on a card and the cards are placed in the envelopes of the letter, respectively. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the time of registration of participants, based on the order in which eligible participants enter the study, one of the envelopes of the letter is opened in order and the assigned group of the

participant is revealed.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Evaluation and treatment are performed by two people. The person evaluating and analyzing the data are those who do not know about grouping. The evaluator is present in the research only at the time of evaluation (before and after treatment).

## 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

Nezam Ave, Madar Blvd, Mirdamad

##### City

Tehran

##### Province

Tehran

##### Postal code

15459-13487

#### Approval date

2020-11-06, 1399/08/16

#### Ethics committee reference number

IR.IUMS.REC.1399.744

## 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

pain

#### Timepoint

At the beginning and the end of each session and two months after the end of the last treatment session

#### Method of measurement

visual analogue scale

## Secondary outcomes

### 1

#### Description

Grip strength

#### Timepoint

At the beginning and the end of each session and two months after the end of the last treatment session

#### Method of measurement

Hand held dynamo meter

### 2

#### Description

Functional status scale of Boston questionnaire

#### Timepoint

Before treatment, at the end of third session and two months after the end of the last treatment session

#### Method of measurement

Persian Boston Questionnaire

### 3

#### Description

Symptom severity scale of Boston Questionnaire

#### Timepoint

Before treatment, at the end of third session and two months after the end of the last treatment session

#### Method of measurement

Persian Boston Questionnaire

## Intervention groups

### 1

#### Description

In this study, TECAR (winback made in France) is used. The frequency used is 300 kHz which is selected due to the use of metal electrodes and the lack of high heat and burns. The patient is asked to sit on a chair and put their hand in supine position comfortably on a table in front of them. Current is applied to the transverse ligament of the wrist for 20 minutes using a resistance electrode with gel. The counter electrode is placed on the dorsal surface of the wrist. Treatment is done in 5 sessions and 2 times a week. In order to perform the neurodynamic technique of the median nerve, the patient is first asked to lie in supine position on the treatment bed. The therapist is then placed next to the bed and the patient's shoulder is taken to the depression. Meanwhile, the arm is placed in abduction and external rotation. In the next step, the forearm is taken to supination. Finally, while the patient's elbow is flexed, the wrists and fingers are extended. Then, by extending the patient's elbow, therapist flex the wrists and fingers. The speed and intensity of the movement should be such that it does not cause pain to the patient. Treatment is done in 5 sessions 2 times a week. The technique is applied in each session in 3 sets of 60 with a 30 second interval between each set.

#### Category

Treatment - Other

### 2

#### Description

Control group: placebo TECAR with neurodynamic techniques, Placebo TECAR is applied by the therapist to the transverse ligament of the wrist. All of the parameters similar to the treatment group, are performed on the transverse ligament of the wrist for 20 minutes but TECAR is silent. After the TECAR therapy the neurodynamic technique of median nerve slippage is performed. A total of 6 sessions of treatment are performed. Each session is 60 minutes.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Physiotherapy Clinic of Iran University

##### Full name of responsible person

Seyyede Elnaz Hashemi

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Nezam Ave, Madar square, Mirdamad

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr,Seyyed Abbas Motevalian

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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**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Seyyede Elnaz Hashemi  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

### Title and more details about the data/document

All data can be shared after identifying individuals.

### When the data will become available and for how long

6 months after printing the results

### To whom data/document is available

The information is available to all researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

It is possible only by mentioning the name and organizational affiliation of the executor and colleagues of the project.

**From where data/document is obtainable**

M.yassin.pt@gmail.com

**What processes are involved for a request to access data/document**

If the data is used in scientific and therapeutic activities, the information is provided to individuals as soon as possible.

**Comments**