

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The comparative evaluation of the effects of TECAR therapy and conventional physical therapy treatments on pain and function in people with Carpal tunnel syndrome

Protocol summary

Study aim

average pain score, hand function index and grip strength in people with carpal tunnel syndrome before and after treatment in both groups

Design

simple, non-random, continuous and goal-based. random blocks (4 blocks of 11 numbers) will be used. Half of the total sample are randomly selected (through the table of random numbers) and are considered as the first group, and the remaining numbers are included in the second group.

Settings and conduct

This study is a randomized clinical trial in a three-way blind method. For this reason, it is considered triple blind that the evaluator, the statistical consultant and the participants are unaware of the type of treatment and treatment groups. This research is conducted in Dr. Taheri's physiotherapy clinic.

Participants/Inclusion and exclusion criteria

Entry requirements:- Carpal tunnel syndrome moderate to severe symptoms - 25-65 years- Burning pain with tingling and numbness in the terminal path of the median nerve - Period of symptoms more than three months Exit conditions: Metabolic and systemic- Polyneuropathy- Corticosteroid injection in the studied hand during the last three months- History of trauma to the involved hand during the last 12 months- Previous surgery related to carpal tunnel syndrome in the involved hand- Heart pacemaker- Severe neurological disease- Pregnancy during the study period- Deformity in the wrist and hand

Intervention groups

both groups will be treated with conventional physiotherapy along with placebo therapy for 10 sessions during 4 weeks (each week includes 3 treatment sessions). For the second group, in addition to the usual physiotherapy treatment, 5 sessions of TECAR

therapy (one session in between) will also be done

Main outcome variables

Pain Symptom severity and hand function Hand strength

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230724058902N1**

Registration date: **2023-07-29, 1402/05/07**

Registration timing: **prospective**

Last update: **2023-07-29, 1402/05/07**

Update count: **0**

Registration date

2023-07-29, 1402/05/07

Registrant information

Name

Elham Tahmasebi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 323 9613

Email address

e.tahmasebi@rehab.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-31, 1402/05/09

Expected recruitment end date

2023-12-30, 1402/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparative evaluation of the effects of TECAR therapy and conventional physical therapy treatments on pain and function in people with Carpal tunnel syndrome

Public title

The comparative evaluation of the effects of TECAR therapy and conventional physical therapy treatments on pain and function in people with Carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Moderate to severe carpal tunnel syndrome based on electrodiagnostic findings 25-65 years old people Tingling pain with pins and needle sensation and numbness in thumb, index, middle and radial half of ring finger Presence of symptoms more than 3 months

Exclusion criteria:

Metabolic and systemic disorder: hypothyroidism, diabetes, rheumatoid arthritis Polyneuropathy Corticosteroid injection in the subject hand in the past 3 months Trauma history to the subject hand in past 12 months Past carpal tunnel syndrome surgery history in the affected hand Pace maker Severe neurologic disorder Pregnancy in study process Deformity in wrist or hand

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a randomized clinical trial in a three-way blind method. The sampling method of this research project is simple, non-random, continuous and goal-based, but the grouping of participants is done in random blocks (4 blocks of 11 numbers). Half of the total sample numbers are randomly selected (through the table of random numbers) and are considered as the first group, and the remaining numbers are included in the second group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study is considered triple-blind because the

evaluator, statistical consultant, and participants are unaware of the type of treatment and treatment groups.

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

East namdaran

City

Fooladshahr

Province

Isfahan

Postal code

8491787543

Approval date

2023-07-24, 1402/05/02

Ethics committee reference number

IR.MUI.NUREMA.REC.1402.058

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

Beginning, after 10 sessions and 4 weeks later

Method of measurement

NPRS

2**Description**

Function

Timepoint

Beginning, after 10 sessions and 4 weeks later

Method of measurement

Boston questionnaire

3

Description

Hand grip strength

Timepoint

Beginning, after 10 sessions and 4 weeks later

Method of measurement

Dynamometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 10 sessions routine physiotherapy - 5 minutes of non-continuous ultrasound (1:4) (manufactured by Novin Medical Engineering Company, model 215M) with a frequency of 1 MHz and an intensity of 21 W/cm on the palmar surface of the wrist / 5 minutes of non-continuous ultrasound (1:4) (manufactured by the company Novin Medical Engineering Model 215M) with a frequency of 1 MHz and an intensity of W/cm21 on the palmar surface of the wrist / - 5 minutes of non-continuous ultrasound (1:4) (manufactured by Novin Medical Engineering Company, model 215M) with a frequency of 1 MHz and an intensity of W/cm21 on the surface Palmar wrist/ therapy exercise program/ along with 5 sessions of TECAR therapy, each session will be 10 minutes (5 minutes of capacitance and 5 minutes of resistance) with a frequency of 500 KHz.

Category

Treatment - Devices

2

Description

Control group: 10 sessions routine physiotherapy - 5 minutes of non-continuous ultrasound (1:4) (manufactured by Novin Medical Engineering Company, model 215M) with a frequency of 1 MHz and an intensity of 21 W/cm on the palmar surface of the wrist / 5 minutes of non-continuous ultrasound (1:4) (manufactured by the company Novin Medical Engineering Model 215M) with a frequency of 1 MHz and an intensity of W/cm21 on the palmar surface of the wrist / - 5 minutes of non-continuous ultrasound (1:4) (manufactured by Novin Medical Engineering Company, model 215M) with a frequency of 1 MHz and an intensity of W/cm21 on the surface Palmar wrist/ therapy exercise program/ along with 5 sessions of placebo TECAR therapy

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Navid Taheri Physiotherapy Clinic

Full name of responsible person

Dr. Navid Taheri

Street address

Mohtasham kashani street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Qolamreza Asgari

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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
Navid Taheri
Position
Associate professor
Latest degree
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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)

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable