Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 21 2222 8052

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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 ol 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

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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Email
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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

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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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