Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of Clemastine effects on clinical and electrodiagnostic parameters in Carpal tunnel syndrome (CTS) patients: A double blind RCT

Protocol summary

Study aim
The practical purpose of this study is that in the future, clemastine can be used as a suitable drug treatment to improve the symptoms of carpal tunnel syndrome patients.

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2-3 on 20 patients. The rand function of Excel software was used for randomization.

Settings and conduct
Physical medicine clinic of Firouzgar Hospital meeting the inclusion criteria , obtaining informed consent, the patients are assigned to two groups of cases and controls based on computer randomization. All patients take apparently similar treatment and will not know whether they are in the control group or the sample group.

Participants/Inclusion and exclusion criteria
Complaint of pain or paresthesia distal to the wrist, or loss of sensation or weakness of thenar muscles - which is accompanied by one of the two positive specific examinations for Carpal tunnel syndrome(CTS) (Tinel, Phalen) No clinical evidence of radicular pain or cervical radiculopathy No history of CTR surgery The patient's willingness to participate in the research project Not receiving injections near the carpal tunnel in the last 3 months Absence of contraindications to the use of clemastine, such as sensitivity to antihistamines

Intervention groups
Therapeutic intervention in the Case group: use of 1 mg clemastine tablets every night along with CTS split for three months, Control group: use of a placebo tablet without active pharmaceutical ingredient, consisting of starch and with an appearance completely similar to the drug, taken every night for three months along with the same splint as the Case group. The prescribed splint for all study patients is the same type of Prefabricated volar cockup wrist splint

Main outcome variables
VAS pain score Median SNAP Amp. Median SNAP Latency Median CMAP Amp. Median CMAP Onset Latency

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190428043404N2**
Registration date: **2023-04-23, 1402/02/03**
Registration timing: **prospective**

Last update: **2023-04-23, 1402/02/03**
Update count: **0**

Registration date
2023-04-23, 1402/02/03

Registrant information

Name
Golam Reza Raissi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2023-11-22, 1402/09/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Clemastine effects on clinical and electrodiagnostic parameters in Carpal tunnel syndrome (CTS) patients: A double blind RCT

Public title

Evaluation of Clemastine effects in CTS pateints

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pain or paresthesia or hypoesthesia in distal hand region or thenar weakness, with positive tinel or phalen tests No clinical evidence of cervical radiculopathy or radicular pain Negative history for Carpal Tunnel Release (CTR) surgery No injection inside or in proximity of carpal tunnel in last 3 months No present contraindication for Clemastine, such as drug allergy to antihistamine group Patient is willing to knowingly participate in a clinical trial

Exclusion criteria:

Patient isn't cooperative for questionnaire completion Drug or alcohol addiction Major depressive disorder or uncontrolled psychiatric disorders Positive history for malignancy or infection in wrist or hand region History of ischemic or neurovascular injury in wrist or hand region Usage of other treatment measures during trial period Patient doesn't follow correct treatment plan regarding drug or splint usage

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned to case and control groups based on computer randomization. The group matching method will be used to control confounding variables (age and gender, body mass index) in two groups. Also, for the purpose of allocation concealment, the assignment of patients to two control and sample groups will be done randomly by someone other than the researcher, and until after the end of the treatment and the analysis, the patient and the therapist will not know the type of treatment (drugs or placebo)

Blinding (investigator's opinion)

Double blinded

Blinding description

Regarding the double-blindness of this study, it should be noted that all patients receive apparently similar treatment (completely identical appearance and prescription for placebo and drug) and despite the patient's knowledge of the study and the possibility of receiving a placebo, being in the control group or the sample group will not be known to patients. In order to blind the Assessor, the therapist and the main analyst will not know about the group assigned to each patient, and the delivery of the drug or placebo to the patient will be the responsibility of another person.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Iran university of medical sciences, School of Medicin

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Iran University of Medical Sciences Shahid Hemmat Highway Tehran 14496-14535, IRAN

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Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2022-12-21, 1401/09/30

Ethics committee reference number

IR.IUMS.FMD.REC.1401.477

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

Patient's pain intensity(Visual Analogue Scale)

Timepoint

Before, after one month and after three months of intervention

Method of measurement

Using the Visual Analogue Scale

2

Description

Median nerve sensory action potential amplitude

Timepoint

Before, after one month and after three months of intervention

Method of measurement

Nerve conduction study

3

Description

Median nerve sensory action potential latency

Timepoint

Before, after one month and after three months of intervention

Method of measurement

Nerve conduction study

4

Description

Median nerve motor action potential latency

Timepoint

Before, after one month and after three months of intervention

Method of measurement

Nerve conduction study

5

Description

Median nerve motor action potential amplitude

Timepoint

Before, after one month and after three months of intervention

Method of measurement

Nerve conduction study

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1 mg clemastine tablet every night along with CTS night splint (Volar cockup wrist splint, Prefabricated) for three months.

Category

Treatment - Drugs

2

Description

Control group: Taking a placebo tablet without active pharmaceutical ingredient (placebo) consisting of starch and with an appearance completely similar to the original drug, every night for three months along with a splint similar to the Case group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Dr.Gholamreza Raissi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
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

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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
All data on study participants and clinical trial information can be shared after de-identification.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Each potential individual with the approval of the

principal investigators

Under which criteria data/document could be used

There will be no exclusive criteria for data usage

From where data/document is obtainable

raissi.gh@iums.ac.ir kzm.kamyar@gmail.com

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

Sending the official request by email Data will be sent to you after the confirmation of the researcher

Comments