Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of effectiveness of L-carnitine with placebo in improving symptoms, electrodiagnostic study and sonographic parameters in patient with carpal tunnel syndrome

Protocol summary

Study aim
Assessment of L-carnitine effect on carpal tunnel syndrome
Design
In this study, 30 patients with mild to moderate CTS with inclusion criteria, are devided into two groups of 15 randomly; the first group receive oral L-carnitine and second group use placebo
Settings and conduct
This randomized clinical trial that will be conducted on referrals to Physical medicine and rehabilitation clinics of shiraz university of medical science
Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged 18 to 65 years old whose mild or moderate CTS is confirmed by electrodiagnostic study and clinical signe and symptoms Exclusion criteria: diseases such as diabetes mellitus, hypothyroidism, rheumatic diseases or any diseases that cause neuropathy Patients who use chemotherapy drugs or any drug that cause neuropathy Pregnant or breast feeding women, body mass index >40 and <18 History of seizure, drug allergy or uncontrolled blood pressure
Intervention groups
First group received L-carnitine Second group received placebo
Main outcome variables
electrodiagnostic and sonograghic parameters of median nerve at wrist, pain and function

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200307046711N1**
Registration date: **2020-04-01, 1399/01/13**
Registration timing: **retrospective**
Last update: **2020-04-01, 1399/01/13**
Update count: **0**
Registration date
2020-04-01, 1399/01/13

Registrant information
Name
Narges Nikpay
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3231 9040
Email address
n_nikpay@sums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-05-15, 1398/02/25
Expected recruitment end date
2020-03-02, 1398/12/12
Actual recruitment start date
2019-05-15, 1398/02/25
Actual recruitment end date
2020-03-02, 1398/12/12
Trial completion date
2020-05-14, 1399/02/25

Scientific title
Comparison of effectiveness of L-carnitine with placebo in improving symptoms, electrodiagnostic study and sonographic parameters in patient with carpal tunnel syndrome

Public title
Effect of L-carnitine in carpal tunnel syndrome
Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Parsons who there CTS is confirmed by electrodiagnostic study and clinical signe and symptoms Patients who aged 18 to 65 years old

Exclusion criteria:

Diseases such as diabetes mellitus, hypothyroidism, rheumatologic diseases, end stage renal disease Patients who use chemotherapy drugs or any drug that cause neuropathy Pregnant or breast feeding women History of seizure Bon mass index > 40 or <18 History of drug allergy Uncontrolled blood pressure

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization: with regard to the numbers of treatment groups (2 groups), we considered blocks with size of four, the first group is shown with A and second with B, then determines formation of persons in groups by using random allocation software

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of shiraz university of medical sciences

Street address

Fars province, shiraz, zand

City

Shiraz

Province

Fars

Postal code

۷۱۳۴۸-۱۴۳۳۶

Approval date

2019-05-15, 1398/02/25

Ethics committee reference number

IR.SUMS.MED.REC.1398.109

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

electrodiagnostic parameters

Timepoint

Before intervention, 4 then 6 weeks after onset

Method of measurement

Electrodiagnostic instruments

2

Description

Hand pain and function

Timepoint

before intervention, 4 then 6 weeks after onset

Method of measurement

Boston questioner

3

Description

cross sectional area of median nerve at wrist

Timepoint

Before intervention, 4 then 6 weeks after onset

Method of measurement

Sonography instrument

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: received L-carnitine، coren company, 500 mg twice per day for 6 weeks, combination of metionin and lysine amino acid,

Category

Treatment - Drugs

2

Description

Intervention group: received placebo, that is made by Dr.Zare pharmacy and containing starch capsules

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics of Physical medicine and rehabilitation of shiraz university of medical science

Full name of responsible person

Alireza Ashraf

Street address

Zand street , Shiraz town

City

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71348-14336

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N_nikpay@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Basir hashemi

Street address

Zand street, shiraz

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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

Shiraz University of Medical Sciences

Proportion provided by this source

50

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

Shiraz University of Medical Sciences

Full name of responsible person

Narges Nikpay

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Narges Nikpay

Position

Resident

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Person responsible for updating data

Contact

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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
Not applicable

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