

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 divided 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 signs 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 sonographic 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**

Shiraz

**Province**

Fars

**Postal code**

71348-14336

**Phone**

+98 71 3231 9040

**Fax**

+98 71 3235 9317

**Email**

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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**Postal code**

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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**

No. 3 , Abiverdi 3, chamran Blvd, shiraz, fars

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Shiraz

**Province**

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**Postal code**

7194765748

**Phone**

+98 71 3231 9040

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

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Resident

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## Person responsible for updating data

N\_Nikpay@sums.ac.ir

### Contact

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**Email**

## 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