

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the Effect of Vitamin B6 Supplement in Comparison to L-acetyl-carnitine on Improvement of Patients with Carpal Tunnel Syndrome

Protocol summary

Study aim

Investigation of the Effect of Vitamin B6 Supplement in Comparison to L-acetyl-carnitine on Improvement of Patients with Carpal Tunnel Syndrome

Design

Two arm parallel group randomized clinical trial with blinded outcome assessment enrolled 60 patients. Randomization is centralized and computerized with block permutation and random allocation software respectively.

Settings and conduct

Patients with mild to moderate symptoms of carpal tunnel syndrome that is proven in electrodiagnostic studies, divided in 2 groups. One group will received 120 mg Vitamin B6 daily and the other group received 1500 mg L-acetyl-carnitin. Both group will received their supplements with splint for 10 weeks. Patients will assessed before beginning the treatment, 10 and 18 weeks later with electrodiagnostic study and 2 specific questionnaires (Visual Analog Scale and Boston Carpal Tunnel Questionnaire). In this study person who fulfills the questionnaires and analyzer are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: mild to moderate carpal tunnel syndrome that confirmed with electrodiagnostic study within last 2 months in patients with age between 30 to 60. Exclusion criteria: severe carpal tunnel syndrome, muscle atrophy, history of surgery, injection or trauma, history of systemic disease.

Intervention groups

One group received 120 mg Vitamin B6 per day and other group received 1500 mg L-acetyl-carnitine for 10 weeks

Main outcome variables

Evaluation of Median sensory nerve action potential (SNAP) in electrodiagnostic studies before and after treatment; Assessment of scores of the questionnaires

before and after treatment

General information

Reason for update

Acronym

CTS

IRCT registration information

IRCT registration number: **IRCT20210915052494N1**

Registration date: **2021-11-04, 1400/08/13**

Registration timing: **prospective**

Last update: **2021-11-04, 1400/08/13**

Update count: **0**

Registration date

2021-11-04, 1400/08/13

Registrant information

Name

Navid Parsa

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4464 1961

Email address

dr.parsanavid@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Investigation of the Effect of Vitamin B6 Supplement in Comparison to L-acetyl-carnitine on Improvement of Patients with Carpal Tunnel Syndrome

Public title
Effect of Vitamin B6 and L-acetyl-carnitin in Treatment of Carpal Tunnel Syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Mild or Moderate Carpal Tunnel Syndrome Disease Proved with Electrodiagnostic Study within Last 2 Months Patients Age Ranges from 30-60

Exclusion criteria:

Severe Carpal Tunnel Syndrome Muscle Atrophy History of Carpal Tunnel Syndrome surgery History of Trauma History of Fracture History of Direct Injection of Carpal Tunnel History of Recent Usage of Corticosteroids and Analgesics Diabetes Collagen Vascular Disorders Rheumatologic Disorders Active Radiculopathy Past Medical History of Brucellosis Pregnancy Lactation Alcoholism Nerve Injury Neuropathy Inability in Communication and Fulfilling Questioners History of Allergic Reaction to Studied Medications History of Significant Liver, Kidney or Cardiovascular Disease Cancer History of Injection Around Wrist within 3 Last Months

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Block permutation with 4 samples in each block will be used. 2 final lists with using random allocation software will be made. For allocation concealment, randomized sequence is given to an uninformed person (etc; clinic secretary)

Blinding (investigator's opinion)
Single blinded

Blinding description
The person who fills the questionnaires and static analyzer are blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Physical medicine and rehabilitation Department, Faghihi hospital, Zand Blvd

City

Shiraz

Province

Fars

Postal code

713484411

Approval date

2021-06-14, 1400/03/24

Ethics committee reference number

IR.SUMS.MED.REC.1400.212

Health conditions studied

1

Description of health condition studied

Carpal tunnel syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Latency of Median sensory nerve action potential

Timepoint

Before the treatment, 10 and 18 weeks after beginning treatment

Method of measurement

Electromyography-Nerve conduction study (EMG-NCV) machine

2

Description

Score of clinical symptoms (like pain and paresthesia) in questionnaires

Timepoint

Before the treatment, 10 and 18 weeks after beginning treatment

Method of measurement

Visual Analogous Scale and Boston Carpal Tunnel Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: 120 mg Vitamin B6 Janilous pharmaceutical Co. daily and splint for 10 weeks

Category

Treatment - Drugs

2

Description

Second intervention group: 1500 mg L-acetyl-carnitine Dana pharmaceutical Co. daily and splint for 10 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faghihi hospital

Full name of responsible person

Navid Parsa

Street address

Faghihi hospital, Zand Ave

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7113484411

Phone

+98 71 3231 9040

Email

faghihihsp@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaian Zade

Street address

Research department, Shiraz University of Medical Science, Zand Blvd

City

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Province

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Postal code

7113484411

Phone

+98 71 3212 2686

Email

researchethic@sums.ac.ir

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

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

Shiraz University of Medical Sciences

Full name of responsible person

Navid Parsa

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

No. 50, Golestan 4th alley, Nahid Ave, Marzadaran

City

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1461643744

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Navid Parsa

Position

Resident

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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 the data will be shared after masking the identity of participants

When the data will become available and for how long

The information will be available 3 months after print

To whom data/document is available

All the researchers and physicians

Under which criteria data/document could be used

Only for research purposes

From where data/document is obtainable

dr.parsanavid@gmail.com Navid Parsa

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

After receiving the email, information will be given in less than one week.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Navid Parsa

Position

Resident

Latest degree

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Other areas of specialty/work

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