Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 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
City
Shiraz
Province
Fars
Postal code
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
Shiraz
Province
Fars
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, Marzdaran
City
Tehran
Province
Tehran
Postal code
1461643744
Phone
+98 21 2201 9258
Email
dr.parsanavid@gmail.com

Person responsible for scientific 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, Marzdaran

City
Tehran

Province
Tehran

Postal code
1461643744

Phone
+98 21 2201 9258

Email
dr.parsanavid@gmail.com

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
Medical doctor

Other areas of specialty/work
Physical Medicine

Street address
No. 50, Golestan 4th alley, Nahid Ave, Marzdaran

City
Tehran

Province
Tehran

Postal code
1461643744

Phone
+98 21 2201 9258

Email
dr.parsanavid@gmail.com

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