Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of rosuvastatin with dose 40 mg compared to placebo on nerve conduction velocity in64 patients with carpal tunnel syndrome

Protocol summary

Study aim

Determining the effectiveness of Rosvastatin 40 mg compared to placebo on the parameters of electrodiagnostic tests (nerve conduction velocity) of 64 patients with carpal tunnel syndrome who referred to the neuromuscular strip clinic of Bu Ali Hospital, Qazvin University of Medical Sciences in 2014-2014

Design

In this study, the effect of Rosvastatin drug on people with CTS confirmed by electrodiagnostic test with different intensity will be investigated. The drug is evaluated in 40 mg scale. And also one group is considered as receiving placebo. 64 patients are divided into two groups of rosuvastatin with two doses of 40 mg and placebo based on random allocation.

Settings and conduct

In a three-way blind randomized clinical trial study (patient and study designer), the study population was among people with CTS who referred to the EMG-NCV clinic of Bo Ali Hospital with mild to moderate severity and who had not received any medical or surgical intervention until the time of referral. have not been selected.

Participants/Inclusion and exclusion criteria

People referring to the EMG-NCV clinic of Bo Ali Hospital who have suspected symptoms of carpal tunnel syndrome in terms of clinical symptoms (including pain, paresthesia, and numbness in the area of the median nerve) are initially included in this study as CTS first. EXCLUDED CRITERIA includes the following: 1- The studied subjects should not be treated with any drug from the statin group. 5- People with cts with severe grade

Intervention groups

this study includes 2 population groups, including people who receive a dose of 40 mg of medicine and people who are treated with placebo.

Main outcome variables

Age/sex/Drug dose/grade cts/Duration of illness/BMI/AMPLITUDE of the median nerve/LATENCY median nerve

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231020059773N1**
Registration date: **2023-12-11, 1402/09/20**
Registration timing: **prospective**

Last update: **2023-12-11, 1402/09/20**
Update count: **0**

Registration date

2023-12-11, 1402/09/20

Registrant information

Name

Farnaz Alidaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 5575

Email address

farnaz.alidae@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-19, 1402/10/29

Expected recruitment end date

2025-09-21, 1404/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of rosuvastatin with dose 40 mg compared to placebo on nerve conduction velocity in64 patients with carpal tunnel syndrome

Public title
Effect of rosuvastatin with dose 40 mg compared to placebo on nerve conduction velocity in64 patients with carpal tunnel syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People who, in terms of clinical symptoms, have suspicious symptoms related to carpal tunnel syndrome (including pain, paresthesia, and numbness in the area of the median nerve) People whose CTS is confirmed by electrodiagnostic tests.

Exclusion criteria:
- Subjects should not be treated with any drug from the statin group. people with hypothyroidism people with connective tissue diseases people with rheumatoid arthritis people with malignancy including Lipoma/ hemangioma / people with infectious and inflammatory diseases including sarcoidosis/ septic arthritis any trauma and local bleeding hemodialysis/ pregnancy/ any conditions that cause edema and increase in total body fluid people with cts with grade severe refers to this group in terms of clinical symptoms of people who have hypotrophy and atrophy of the thenar muscle or people who were classified as grade/severe based on electrodiagnostic tests

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **64**
More than 1 sample in each individual
Number of samples in each individual: **2**
The method of evaluating the effect of the drug on these people is measured by performing NCV and evaluating the median nerve AMPLITUDE/LATENCY. Thus, NCV is collected from patients once before receiving the drug and again 3 months after receiving the drug.

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the effect of Rosvastatin drug on people with CTS confirmed by electrodiagnostic test with different intensity will be investigated. This study includes 2 population groups, including people who receive a dose of 40 mg of medicine and people who are treated with placebo. The way of selecting people to receive medicine or placebo follows the law of random allocation. In this way, the total sample size in this study is about 64 people with cts People are randomly divided into two groups of 32 people (group a to receive medicine / group b to receive placebo)

Blinding (investigator's opinion)
Single blinded

Blinding description
The method of blinding in this study is designed as single blind. This means that only the participants of this study do not know which group they are in (receiving medicine or placebo). In this study, the researcher/clinical caregiver/outcome assessor/data analyst and the data safety and integrity committee are aware of the allocation of groups

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences and Health Services

Street address
2nd floor-No.15-30 corner-Rashid Street-Tehranpars-Tehran

City
Tehran

Province
Tehran

Postal code
1651774944

Approval date
2023-10-14, 1402/07/22

Ethics committee reference number
IR.QUMS.REC.1402.184

Health conditions studied

1

Description of health condition studied
Carpal tunnel syndrome

ICD-10 code
G56.00

ICD-10 code description
Carpal tunnel syndrome, unspecified upper limb

Primary outcomes

1

Description
Severity of carpal tunnel disease
Timepoint
Start of the study/three months after the start of the study
Method of measurement
Electrodiagnostic tests/questionnaire

2

Description
AMPLITUDE of Median nerve
Timepoint
Start of the study/three months after the start of the study
Method of measurement
Electrodiagnostic tests/questionnaire

3

Description
LATENCY of Median nerve
Timepoint
Start of the study/three months after the start of the study
Method of measurement
Electrodiagnostic tests/questionnaire

4

Description
BMI
Timepoint
Start of the study
Method of measurement
questionnaire

Secondary outcomes

1

Description
Reduction of clinical symptoms of patients including paresthesia and pain and...
Timepoint
Beginning of the study/ three months after the beginning of the study
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group: Patients receiving Rosuvastatin 40 mg
Category
Treatment - Drugs

2

Description
Control group: receiving a placebo drug
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Boali Qazvin Hospital
Full name of responsible person
Farnaz Alidaee
Street address
in front of Mehrgan Hospital- Ferdowsi Street -Qazvin Town
City
Ghazvin
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Qazvin
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3413786165
Phone
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Email
farinooshAlidae@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr. Roghieh Mehrdal
Street address
in front of Mehrgan Hospital- Ferdowsi Street - Qazvin Town
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3413786165
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Email
drmehrdel@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Farnaz Alidaee

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Farnaz Alidaee

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

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