

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of rosuvastatin with dose 40 mg compared to placebo on nerve conduction velocity in 64 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.alidaee@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 in 64 patients with carpal tunnel syndrome

Public title

Effect of rosuvastatin with dose 40 mg compared to placebo on nerve conduction velocity in 64 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 Mehrigan Hospital- Ferdowsi Street -Qazvin Town

City

Ghazvin

Province

Qazvin

Postal code

3413786165

Phone

+98 28 3332 6032

Email

farinooshAlidaee@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 Mehrigan Hospital- Ferdowsi Street - Qazvin Town

City

Ghazvin

Province

Qazvin

Postal code

3413786165

Phone

+98 28 3332 6032

Email

drmehrdeh@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
Street address
2nd floor-No.15-130 corner-Rashid Street-Tehranpars-Tehran
City
Tehran
Province
Tehran
Postal code
1651774944
Phone
+98 21 7788 5575
Email
farinooshAlidaee@yahoo.com

Person responsible for scientific 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
Street address
2nd floor-No.15-130 corner-Rashid Street-Tehranpars-Tehran
City
Tehran
Province
Tehran

Postal code
1651774944
Phone
+98 21 7788 5575
Email
farinooshAlidaee@yahoo.com

Person responsible for updating data

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
Street address
- - No. 15 - 2nd floor-130 Rashid St. corner-Tehranpars-
City
Tehran
Province
Tehran
Postal code
1651774944
Phone
+98 21 7788 5575
Fax
Email
farnaz.alidaee@gmail.com

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