

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of combination therapy with Atorvastatin and Carnitine versus Atorvastatin alone on lipid profile of hemodialized patients

Protocol summary

Summary

The aim of present study was to compare combination therapy with Atorvastatin and Carnitine versus Atorvastatin alone on lipid profile of hemodialized patients. In a single center clinical trial study, 50 hemodialized patients who referred to Imam-Reza Hospital of Tabriz University of Medical Sciences will select randomly and with using random numbers table will allocate in two groups of intervention and control group. Inclusion criteria are, hemodialized patients, age between 18 to 75 years old, and informed consent form for participating in study. Exclusion criteria is using any medication which effect on lipid profile of patients. In intervention group patients will receive 10 to 80 mg Atorvastatin daily (based on primary lipid profile level) with 1000 mg Carnitine three times in a day with daily meal. In control group patients receive only 10 to 80 mg Atorvastatin daily (based on primary lipid profile level). Patients will follow up for 6 months. Lipid profile level will measure at beginning of study, first month, third month, and also at the end of 6th month. Decrease in lipid profile level is as primary variable of study and side effect is as secondary variable of present study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604273742N3**

Registration date: **2016-05-14, 1395/02/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-05-14, 1395/02/25

Registrant information

Name

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Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences.

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of combination therapy with Atorvastatin and Carnitine versus Atorvastatin alone on lipid profile of hemodialized patients

Public title

Comparison of combination therapy with Atorvastatin and Carnitine versus Atorvastatin alone on lipid profile of hemodialized patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: hemodialized patients; age between 18 to 75 years old; informed consent form for participating

in study. Exclusion criteria: using any medication which effect on lipid profile of patients.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences.

Street address

Tabriz University of Medical Sciences, Daneshgah
Street, Tabriz, Eastern Azerbaijan, Iran.

City

Tabriz

Postal code

Approval date

2015-11-23, 1394/09/02

Ethics committee reference number

TBZMED.REC.1394.767

Health conditions studied

1

Description of health condition studied

Hyperlipidaemia

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidaemia, unspecified

Primary outcomes

1

Description

Triglyceride

Timepoint

Beginning of study, first month, third month, 6th month.

Method of measurement

milligrams per deciliter

2

Description

high density lipoprotein (HDL)

Timepoint

Beginning of study, first month, third month, 6th month.

Method of measurement

milligrams per deciliter

3

Description

low density lipoprotein (LDL)

Timepoint

Beginning of study, first month, third month, 6th month.

Method of measurement

milligrams per deciliter

4

Description

total cholesterol

Timepoint

Beginning of study, first month, third month, 6th month.

Method of measurement

milligrams per deciliter

Secondary outcomes

1

Description

Adverse effects

Timepoint

First month, third month, 6th month.

Method of measurement

History and clinical examination

Intervention groups

1

Description

In intervention group: Patients will receive 10 to 80 mg Atrovastatine daily based on primary lipid profile with 1000 mg Carnitine three times in a day for six months.

Category

Treatment - Drugs

2

Description

In control group: Patients will receive 10 to 80 mg Atrovastatine daily based on primary lipid profile for six

months.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam-Reza Hospital

Full name of responsible person

Dr Hamid Noshad

Street address**City**

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Tabriz University of Medical Sciences.

Full name of responsible person

Dr Hasan Soleimanpour

Street address

Deputy of Research and Technology, Central Building of Number Two, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz.

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Tabriz University of Medical Sciences.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences.

Full name of responsible person

Dr Davoud Mohammadi Nejad

Position

Assistant of Internal Medicine

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty