

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

The effect of Rosvastatin on steatosis and fibrosis in patients with non-alcoholic fatty liver disease: a randomized controlled clinical trial study

Protocol summary

Summary

The aim of this randomized controlled clinical trial study was to evaluate the effect of Rosvastatin on steatosis and fibrosis in patients with non-alcoholic fatty liver disease. From patients who were referred to gastrointestinal clinic of Tohid hospital, Sanandaj, Iran total of 40 patients with non-alcoholic fatty liver disease were selected. Main inclusion criteria included: Non diabetic patients, normal FBS, BS2hpp, Hb1AC, age 20 years and older, approved non fatty liver diagnosed by fibroscan, LFT (AST and ALT), rejection of other causes of fatty liver disease such as hepatitis B and C. Main exclusion criteria included: patients who have other liver diseases, contraindication for Rosvastatin, not taking hypoglycemic drugs such as metformin. Patients randomly divided into intervention and control groups. Patients and researchers were blinded and were not aware of grouping. In intervention group patients received 10 mg Rosvastatin daily plus standard treatment for fatty liver disease. In control group patients received placebo daily plus standard treatment for fatty liver disease. Before intervention and six months after the intervention AST and ALT were controlled and also, liver steatosis and liver fibrosis re-measured by fibroscan.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060212789N14**
Registration date: **2017-06-12, 1396/03/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-12, 1396/03/22

Registrant information

Name

Masoud Rasolabady

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Kurdistan University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-07-20, 1396/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Rosvastatin on steatosis and fibrosis in patients with non-alcoholic fatty liver disease: a randomized controlled clinical trial study

Public title

The effect of Rosvastatin on steatosis and fibrosis in patients with non-alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Main Inclusion Criteria: Non diabetics patients; normal FBS; BS2hpp;Hb1AC; Age 20 years and older; approved non fatty liver diagnosed by fibroscan; LFT(AST and ALT);

rejection of other causes of fatty liver disease such as hepatitis B and C . Main Exclusion Criteria: Patients who have other liver diseases; contraindication for Rosvastatin; not taking hypoglycemic drugs such as metformin.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Iran

City

Sanandaj

Postal code

Approval date

2016-05-01, 1395/02/12

Ethics committee reference number

IR.MUK.REC.1395.284

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver disease (NAFLD)

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

steatosis of liver

Timepoint

Before intervention, six month after intervention

Method of measurement

Fibroscan

2

Description

Fibrosis of liver

Timepoint

Before intervention, six month after intervention

Method of measurement

Fibroscan

Secondary outcomes

1

Description

ALT

Timepoint

Before intervention, six month after intervention

Method of measurement

Blood examination

2

Description

AST

Timepoint

Before intervention, six month after intervention

Method of measurement

Blood examination

3

Description

LDL

Timepoint

Before intervention, six month after intervention

Method of measurement

Blood examination

4

Description

HDL

Timepoint

Before intervention, six month after intervention

Method of measurement

Blood examination

5

Description

Triglyceride

Timepoint

Before intervention, six month after intervention
Method of measurement
Blood examination

6

Description
Bilirubin
Timepoint
Before intervention, six month after intervention
Method of measurement
Blood examination

7

Description
Blood urea
Timepoint
Before intervention, six month after intervention
Method of measurement
Blood examination

8

Description
Blood creatinine
Timepoint
Before intervention, six month after intervention
Method of measurement
Blood examination

Intervention groups

1

Description
Control Group: patients received placebo daily plus standard treatment for fatty liver disease.
Category
Treatment - Drugs

2

Description
Intervention Group: patients received 10 mg Rosvastatin daily plus standard treatment for fatty liver disease.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tohid Hospital
Full name of responsible person
Dr. Nematillah Naghshbandi
Street address
Tohid Hospital, Geryashan St., Basij Sq., Sanandaj,
Iran
City

Sanandaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Kurdistan University of Medical Sciences
Full name of responsible person
Dr. Ebrahim Ghaderi
Street address
Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Iran
City
Sanandaj
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 of Kurdistan 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
Kurdistan University of Medical Sciences
Full name of responsible person
Dr. Nematollah Naghshbandi
Position
Internal Medicine Resident
Other areas of specialty/work
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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Dr. Farshad Sheikhesmaili

Position

Associate Professor

Other areas of specialty/work**Street address**

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr. Nematollah Naghshbandi

Position

Internal Medicine Resident

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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