Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 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

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Position

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Person responsible for scientific inquiries

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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