

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3366 4654

##### Email address

rasolabady@muk.ac.ir

#### 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. Nematollah 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**  
**Street address**  
Tohid Hospital, Geryashan St., Basij Sq., Sanandaj,  
Iran  
**City**  
Sanandaj  
**Postal code**  
**Phone**  
+98 87 3328 6112  
**Fax**  
**Email**  
dr.n.naghshbandi@gmail.com  
**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**

Tohid Hospital, Geryashan St., Basij Sq., Sanandaj,  
Iran

**City**

Sanandaj

**Postal code****Phone**

+98 87 3328 6112

**Fax****Email**

Dr\_S\_Smaili@yahoo.com

**Web page address****Position**

Internal Medicine Resident

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

Tohid Hospital, Geryashan St., Basij Sq., Sanandaj,  
Iran

**City**

Sanandaj

**Postal code****Phone**

+98 87 3328 6112

**Fax****Email****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*

## Person responsible for updating data

### Contact

**Name of organization / entity**

Kurdistan University of Medical Sciences

**Full name of responsible person**

Dr. Nematollah Naghshbandi