

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of combination therapy with Atorvastatin and Aspirin on the severity of fibrosis and liver function in compensated cryptogenic cirrhosis

#### Protocol summary

##### Summary

Objective: The effect of combination therapy with Atorvastatin and Aspirin on the severity of fibrosis and liver function in compensated cryptogenic cirrhosis Study design: Randomized, Double blind, controlled with placebo, single center, Phase 4 trial, Population study: patient with compensated cryptogenic cirrhosis Inclusion criteria: patients with compensated cryptogenic cirrhosis; patients living in Qom; Age of 18 to 75 years; patient without another type of cirrhosis; patients that not medicated with statins; patients with serum LDL>70; Patients with PLT>50000 Exclusion criteria: Increased liver enzymes more than three times, three months after treatment; Lack of cooperation in the proper use of drugs; Statin-induced myopathy; use of Fibrates, Erythromycin, and other drugs that suppressed metabolism of p450 liver enzyme Sample size: 40 patients Intervention: combination therapy with Atorvastatin and Aspirin and Atorvastatin and placebo in control group Outcome: severity of liver fibrosis and liver function

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016120531252N1**  
Registration date: **2017-02-28, 1395/12/10**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-02-28, 1395/12/10

##### Registrant information

Name

Ahmad Hormati

##### Name of organization / entity

Qom university of Medical Sciences

##### Country

Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

Office of Research & Technology; Qom University of Medical Sciences

##### Expected recruitment start date

2017-01-20, 1395/11/01

##### Expected recruitment end date

2017-03-21, 1396/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of combination therapy with Atorvastatin and Aspirin on the severity of fibrosis and liver function in compensated cryptogenic cirrhosis

##### Public title

Effect of Aspirin and Atorvastatin on liver function in patients with hepatic failure

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients with compensated cryptogenic cirrhosis; living in Qom; Age of 18 to 75 years; patient

without another type of cirrhosis; who have not been treated with statins; patients with serum LDL>70; Patients with PLT>50000 Exclusion criteria: Increased liver enzymes more than three times, three months after treatment; Lack of cooperation in the proper use of drugs; Statin-induced myopathy; use of Fibrates, Erythromycin, and other drugs that suppressed metabolism of p450 liver enzyme

**Age**

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

**Gender**

Both

**Phase**

2-3

**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**

Qom University of Medical Sciences

**Street address**

Qom, Saaheli Street, Qom University of Medical Sciences

**City**

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**Postal code**

3713649373

**Approval date**

2017-01-18, 1395/10/29

**Ethics committee reference number**

IR.MUQ.REC.1395.134

**Health conditions studied****1****Description of health condition studied**

Liver Cirrhosis

**ICD-10 code**

K72.1

**ICD-10 code description**

Chronic hepatic failure

**Primary outcomes****1****Description**

sevirity of fibrosis

**Timepoint**

six months after begining intervention

**Method of measurement**

kpa with fibroscan

**2****Description**

liver function

**Timepoint**

six months after begining intervention

**Method of measurement**

child score

**Secondary outcomes****1****Description**

liver enzymes levels

**Timepoint**

six month after begining of intervention

**Method of measurement**

IU/L

**Intervention groups****1****Description**

Atorvastatin, tab 20 mg oral, once daily, for 6 months along with Aspirin, tab 80 mg Oral, once daily, for six months

**Category**

Treatment - Drugs

**2****Description**

Atorvastatin, tab 20 mg, oral, once daily, for 6 months along with placebo (of Aspirin), Oral, once daily, for 6 months

**Category**

Placebo

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

Gastroenterology and Hepatology Research Center,

Qom University of Medical Sciences  
**Full name of responsible person**  
Dr Mansoureh Molaei  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Office of Research & Technology, Qom University of  
Medical Sciences  
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Fahime Aliabadi  
**Street address**  
Number 83, Alley 4, Alley 1.1, Safashahr Street  
**City**  
Qom  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor  
organization/entity?**  
Yes  
**Title of funding source**  
Office of Research & Technology, Qom 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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*