Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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
Qom

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 Cirhhosis

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 Asprin, 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

Street address
Gastroenterology and Hepatology Disease Research Center, Endoscopy Unit, Shahid Beheshti Hospital Qom, Shahid Beheshti Blv

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Office of Research & Technology, Qom University of Medical Sciences

Full name of responsible person
Fahime Aliabadi

Street address
Namber 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

Name of organization / entity
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Full name of responsible person
Mansoureh Molaei

Position
M.D, Resident of Internal Medicine

Other areas of specialty/work

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Assistant Professor of adults Gastroenterology and hepatology

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Position
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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