Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigation the effect of adding Atorvastatin to routine Tenofovir treatment on severity of liver fibrosis and liver function among patients with chronic hepatitis B

Protocol summary

Summary

The main purpose: Effect of adding Atorvastatin to Tenofovir on severity of liver fibrosis and liver function for treatment of patients with chronic hepatitis B. Design: Double blind randomized controlled trial Inclusion criteria: Patients between 18 and 75 years old with chronic hepatitis B for more than 6 months and dysfunction in liver function, serum LDL more than 90 mg/dl Exclusion criteria: Patients with hepatitis B less than 6 months, Inactive carriers of hepatitis B, Patients with no fibrosis and cirrhosis, Patients with decompensated cirrhosis, Patients with chronic liver disease such as willson and hemochromatosis, Patients with hepatic cell carcinoma, Patients with other malignancies, Patients with co-infection and superinfection of HIV ,HCV or HDV, Patients that were treated with Atorvastatin, Pregnant and lactating women, Increasing of liver enzymes 2 times of normal range after 1 months of treatment. Sample size: 80 Patients Intervention: adding Atorvastatin to routine treatment Duration of intervention: 6 months Outcomes: liver function and liver fibrosis

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010631252N3**
Registration date: **2017-03-02, 1395/12/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-02, 1395/12/12

Registrant information

Name

Ahmad Hormati

Name of organization / entity

Qom university of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

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

Investigation the effect of adding Atorvastatin to routine Tenofovir treatment on severity of liver fibrosis and liver function among patients with chronic hepatitis B

Public title

Effect of Atorvastatin on liver function in patients with chronic hepatitis B

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients between 18 and 75 years old with chronic hepatitis B for more than 6 months and

dysfunction in liver function, serum LDL more than 90 mg/dl Exclusion criteria: Patients with hepatitis B less than 6 months, Inactive carriers of hepatitis B, Patients with no fibrosis and cirrhosis, Patients with decompensated cirrhosis, Patients with chronic liver disease such as willson and hemochromatosis, Patients with hepatic cell carcinoma, Patients with other malignancies, Patients with co-infection and superinfection of HIV ,HCV or HDV, Patients that were treated with Atorvastatin, Pregnant and lactating women, Increasing of liver enzymes 2 times of normal range after 1 months of treatment.

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

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
Oom University of Medical Sciences

Street address
Oom University of Medical Sciences, Saheli street, Qom

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3713649373

Approval date
2017-01-14, 1395/10/25

Ethics committee reference number
IR.MUQ.REC.1395.133

Health conditions studied

1

Description of health condition studied
chronic hepatitis

ICD-10 code
K73.0

ICD-10 code description
Chronic persistent hepatitis

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 intervention

Method of measurement
Child score

Secondary outcomes

1

Description
Liver enzymes levels

Timepoint
Six month after begining of intervention

Method of measurement
Blood levels with IU/ml

Intervention groups

1

Description
In intervention group, Atorvastatin tablet, 20 mg, oral, once daily, for six months

Category
Treatment - Drugs

2

Description
In control group, Atorvastatin placebo, oral, once daily, for six 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 Mahdi Jahangiry

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
Qom University of Medical Sciences

Full name of responsible person
Fahime Aliabadi

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Namber 83, Alley 4, Alley 1.1, Safashahr Street

City
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
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
Mahdi Jahangiry

Position
medical doctor, resident of internal medicine

Other areas of specialty/work

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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