

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 25 3612 2053

##### Email address

hormatia@muq.ac.ir

##### 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

**City**

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**Postal code**

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 beginning 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

**City**

Qom

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Qom University of Medical Sciences

**Full name of responsible person**

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**

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**

Qom University of Medical Sciences

**Full name of responsible person**

Mahdi Jahangiry

**Position**

medical doctor, resident of internal medicine

**Other areas of specialty/work**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Qom University of Medical Sciences

**Full name of responsible person**

Ahmad Hormati

**Position**

Assistant Professor of adults Gastroenterology and  
hepatology

**Other areas of specialty/work**

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**Person responsible for updating data**

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Ahmad Hormati

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**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*