Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Feb 2026

The effect of Atorvastatin in combination to Tenofovir in the treatment of Hepatitis B

Protocol summary

Study aim
this study aimed to evaluate the efficacy and safety of 40 mg/day atorvastatin on treatment of hepatitis B patients.

Design
single Blind, randomized clinical trial, with two controll and interventional groups. 40 patients with active hepatitis B were randomly divided into two groups. Random table and epi info software were used for random allocation of patients.

Settings and conduct
Patients with active hepatitis B referred to Shahid Beheshti Hospital Liver and Gastroenterology Clinic were randomly divided into control or intervention groups and treated.

Participants/Inclusion and exclusion criteria
Criteria for entering the study Patients with chronic active hepatitis B are diagnosed with a doctor (gastroenterologist). Patients with hepatitis B that are candidates for anti-viral therapy Viral load greater than 100,000 copy/mL that is determined prior to treatment. HBe Ag negative No symptoms of cirrhosis and fibrosis Exit criteria Increased Hepatic Enzymes (ALT). Severe renal failure Use of immunosuppressive drugs Acquired or congenital immune defects Infections associated with autoimmune hepatitis, drugs, C and D and HIV Taking medication with statins or tenofovir History of taking statins or any other antiviral drug in the last six months Age under 18 years Alcoholic and non-alcoholic liver.

Intervention groups
The atorvastatin treating group recieve standard treatment for chronic HBV (300 mg Tenofovir twice a day) along with 40 mg/day atorvastatin for 12 months while, control group recieve standard regimen in addition to placebo once daily.

Main outcome variables
viral load and liver enzymes.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110621006852N2**
Registration date: **2021-02-28, 1399/12/10**
Registration timing: **retrospective**

Last update: **2021-02-28, 1399/12/10**
Update count: **0**

Registration date
2021-02-28, 1399/12/10

Registrant information

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Mohammad Reza Haeri

Name of organization / entity
Qom University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2013-04-21, 1392/02/01

Expected recruitment end date
2014-04-21, 1393/02/01

Actual recruitment start date
2013-04-21, 1392/02/01

Actual recruitment end date
2014-04-21, 1393/02/01

Trial completion date
2014-04-21, 1393/02/01

Scientific title
The effect of Atorvastatin in combination to Tenofovir in the treatment of Hepatitis B

Public title
The effect of Atorvastatin in combination to Tenofovir in the treatment of Hepatitis B

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with active hepatitis B that are candidates for anti-viral therapy Viral load greater than 100,000 per ml patients with elevated ALT

Exclusion criteria:
All patients with severe kidney failure. Patients who use suppressor drugs for immune system. Patients with acquired or congenital immune deficiencies. Patients who have had a history of taking statins or any other antiviral medicines in the last six months.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **43**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Participating patients did not know which group was preferred and in which group they are in. Only a specialist knew what group each person was. The analyzer also did not have an idea of which group was better or what type of medication was used, and analyzed only two sets of raw data.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qom University of Medical sciences

Street address
Alqadir Bolivard

City
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Province
Ghoum

Postal code
3457731551

Approval date
2015-03-08, 1393/12/17

Ethics committee reference number
IR.MUQ.REC.1393.148

Health conditions studied

1

Description of health condition studied
Liver Disease

ICD-10 code
K71.6

ICD-10 code description
Toxic liver disease with hepatitis, not elsewhere classified

Primary outcomes

1

Description
viral load

Timepoint
At the beginning of the trial and then once every three months interval

Method of measurement
realtime PCR

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiver of tenofuir and atorvastatin. Tenofovir is the standard hepatitis B drug and is a reverse transcriptase nucleotide inhibitor. To maintain ethical standards, patients with hepatitis B are given Tenofovir manufactured by Hetero Healthcare 300 mg twice a day orally and 40 mg of the study drug, atorvastatin, as tablets made by Poursina factory. The duration of treatment with both drugs is 12 months. To detect the amount of virus, PCR tests are performed at times zero, first month, third month, sixth month, ninth month, and finally the twelfth month to measure the number of viruses in the blood and determine the effect of treatment on the number of viruses.

Category
Treatment - Drugs

2

Description
Control group: Tenofovir recipient alone
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Dr. Yazdani
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Shahid Beheshti Hospital, Imam Street, near Azadegan Square
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Sponsors / Funding sources

1

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Name of organization / entity
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Grant name
Research council, Qom University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available