

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 control 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 receive standard treatment for chronic HBV (300 mg Tenofovir twice a day) along with 40 mg/day atorvastatin for 12 months while, control group receive 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

Name

Mohammad Reza Haeri

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4465 1176

Email address

haeri@muq.ac.ir

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

Qom

Province

Ghous

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

Street address

Shahid Beheshti Hospital, Imam Street, near Azadegan Square

City

Qom

Province

Ghous

Postal code

34937157

Phone

+98 25 3291 7376

Email

haeri.mr@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Dr. Ehsan Sharifipour

Street address

Shahid Beheshti Hospital, Imam Street, near Azadegan Square

City

Qom

Province

Ghous

Postal code

34937157

Phone

+98 25 3291 7376

Email

haeri.mr@gmail.com

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

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Mohammad Reza Haeri

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Biochemistry

Street address

Shahid Beheshti Hospital Imam Street, Azadegan Square

City

Qom

Province

Ghous

Postal code

34937157

Phone

+98 25 3291 7376

Email

haeri.mr@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qom University of Medical Sciences

Full name of responsible person

Haeri

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Shahid Beheshti Hospital, Imam Street, near Azadegan Square

City

Qom

Province

Ghous

Postal code

37457731551

Phone

+98 25 3291 7376

Email
haeri.mr@gmail.com

+98 25 3291 7376

Email
haeri.mr@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Mohammad Reza Haeri

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Biochemistry

Street address

School of Medicine, Qom University of Medical Sciences, Al-Ghadir Blvd

City

Qom

Province

Ghoum

Postal code

22857731551

Phone

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