

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of adding Irbesartan to Pegylated Interferon-alpha-2a in Patients With HBeAg Negative Chronic Hepatitis B Co-infected With Hepatitis D

Protocol summary

Summary

Purpose and design of the study: The effect of adding Irbesartan to Pegylated Interferon-alpha-2a in patients with HBeAg negative chronic hepatitis B Co-infected with hepatitis D. Randomized, single-blind, phase II clinical trials. Population of study and procedure: 45 registered patients in Imam Khomeini hospital hepatitis clinic with the main criteria for inclusion: chronic hepatitis B (HBs Ag positive during at least past 6 months) and infection with hepatitis D virus (anti-HDV positive antibodies) for at least 3 months and positive for HDV -RNA in screening period; HBe Ag negative; All women during fertility period should have a negative pregnancy test before registration; Ability to provide written informed consent to participate in the study; and the main exclusion criteria: untreated liver disease; co-infection with hepatitis C or HIV; creatinine clearance <60 ml / min; Patients who are allergic to one of the Irbesartan components; pregnancy and lactation; patients with SBP <110 mm Hg or history of hypotension at any time; are allocated randomly in 3 groups: administration of Irbesartan before treatment followed by Pegylated interferon alfa-a2 versus a combination of both drugs versus Pegylated interferon alfa-a2 alone for 18 months. The serum level of HBsAg is measured after 3 months and 18 months. Outcomes of the study: Adding Irbesartan associates with a low level of serum HBsAg , at least 0.5 log / IU / ml, after 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071128308N3**

Registration date: **2017-08-08, 1396/05/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-08, 1396/05/17

Registrant information

Name

Ali Asadollahi Amin

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7752 0856

Email address

emadiham@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Tehran University of Medical Sciences

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding Irbesartan to Pegylated Interferon-alpha-2a in Patients With HBeAg Negative Chronic Hepatitis B Co-infected With Hepatitis D

Public title

The effect of your Irbesartan drug in treatment of hepatitis B and D

IR.TUMS.IKHC.REC.1396.2967

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: chronic hepatitis B with HBsAg present at least 6 months before screening and infection with hepatitis D virus as anti-HDV positive antibodies for at least 3 months and positive for HDV-RNA in the screening period; HBeAg negative ; All women with fertility potential should have a negative pregnancy test before enrollment; ability to provide informed written consent to participate in the study.Exclusion criteria: untreated liver disease; co-infection with hepatitis C or HIV; Creatinine clearance <60 ml / min; Patients who are allergic to one of the Irbesartan components; Pregnancy and lactation; Patients with SBP <110 mm Hg or history of hypo tension at any time

Age

From **18 years** old to **69 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization is done by Permuted-6th block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hospital Ethics Committee Imam Khomeini, Tehran
University of Medical Sciences

Street address

End of Keshavarz Blvd., Imam Khomeini Hospital .

City

Tehran

Postal code

Approval date

2017-07-25, 1396/05/03

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Hepatitis B and D

ICD-10 code

B18.0

ICD-10 code description

Chronic viral hepatitis B with delta-agent

Primary outcomes

1

Description

HBsAg

Timepoint

Before study, 3 months after, 18 months after

Method of measurement

Blood test, in units per milliliter (IU / ml)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Administration of irbesartan tablet 300 mg daily prior to treatment with pegylated interferon alpha-a2 for 24 weeks, followed by pegylated interferon alfa-a2 weekly at 180mcg alone for 48 weeks

Category

Treatment - Drugs

2

Description

Intervention group2: Concomitant administration of a daily dose of 300 mg of Irbesartan tablet and 180 mcg pegylated alpha-a2 interferon for 24 weeks, followed by pegylated interferon alfa-a2 weekly at 180 mcg alone for 24 weeks

Category

Treatment - Drugs

3

Description

Intervention group3: Treatment with pegylated interferon alfa-a2 weekly at 180mcg alone for 48 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hepatitis clinic of Imam Khomeini Hospital.

Full name of responsible person

Miss Bayani

Street address

Imam Khomeini Hospital, End of Keshavarz Blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Younesian

Street address

Tehran University of Medical Sciences Headquarters, Keshavarz Blvd., First of Ghods St

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research Tehran 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

Tehran University of Medical Science

Full name of responsible person

Dr. Ali Asadollahi Amin

Position

Infectious disease specialist

Other areas of specialty/work**Street address**

Imam Khomeini Hospital, End of Keshavarz Blvd.

City

Tehran

Postal code**Phone**

+98 21 6119 2811

Fax**Email**

amiyaneh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Dr. Ali Asadollahi Amin

Position

Infectious disease specialist

Other areas of specialty/work**Street address**

Imam Khomeini Hospital, End of Keshavarz Blvd.

City

Tehran

Postal code**Phone**

+98 21 6119 2811

Fax**Email**

amiyaneh@gmail.com

Web page address

Person responsible for updating data

Contact

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