# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 registeration; 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**
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**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

**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**

IR.TUMS.IKHC.REC.1396.2967

## 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**

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Imam Khomeini Hospital, End of Keshavarz Blvd.

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amiyaneh@gmail.com

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## 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**

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Imam Khomeini Hospital, End of Keshavarz Blvd.

**City**
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## 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*