

# 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.

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**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*