# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Comparison of Pegylated Interferon alfa-2a plus Adefovir and Pegylated Interferon alfa-2a alone in the treatment of chronic hepatitis B with genotype D (multicenter study)

## Protocol summary

**Summary**

In this multicenter double-blind study, we compare efficacy of Pegylated Interferon alfa-2a plus Adefovir and Pegylated Interferon alfa-2a alone in the treatment of chronic hepatitis B with genotype D in 74 patients. All patients who have chronic hepatitis B based on the liver biopsy, HBsAg positive for more than six months, ALT level more than 1/1 ULN and less than 10 ULN, more than 10000copies/ml, type D genotype will be enrolled in the study. Patients who have treated prior to study, receiving anti neoplastic, anti viral or Immunomedullator drugs during 6 months prior to study, have co-infection Hepatitis A,C,D or HIV, severe liver or renal dysfunction, are pregnant or breast fed, or refuse to sign informed consent will be excluded. These subjects will be allocated into study groups through simple randomization method. One group receives 180 µg/wk Pegylated Interferon alfa-2a plus 10 mg Adefovir and another group receives 180 µg/wk Pegylated interferon alfa-2a alone for 48 week. Patients will be followed for 24 week after treatment. We will compare two groups in terms of their response to treatment. The response to treatment is defined as decrease 2 score in hepatitis activity index, HBV-DNA>200 copies /ml and normal level of ALT

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT138711201155N4**
Registration date: **2009-05-02, 1388/02/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2009-05-02, 1388/02/12

**Registrant information**

**Name**

Farahnaz Joukar

**Name of organization / entity**

Guilan University of Medical Sciences, Gastrointestinal and liver disease Research Center

**Country**

Iran (Islamic Republic of)

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+98 13 1553 5116

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**Recruitment status**

**Recruitment complete**

**Funding source**

Gastrointestinal and Liver Diseases Research Center (GLDRC)

**Expected recruitment start date**

2009-03-09, 1387/12/19

**Expected recruitment end date**

2010-09-09, 1389/06/18

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of Pegylated Interferon alfa-2a plus Adefovir and Pegylated Interferon alfa-2a alone in the treatment of chronic hepatitis B with genotype D (multicenter study)

**Public title**

Effect of Pegylated Interferon alfa-2a plus Adefovir in the treatment of chronic hepatitis B with genotype D

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Presence of hepatitis B for more than 6 month, ALT more than 1/1 normal upper limit and less than 10 ULN, 18<age<65 years, Genotype D, HBV-DNA>10.000 copies/ml. Exclusion criteria: Receiving anti neoplasm, anti viral or immunomedulator drugs during 6 months prior to study, previous treatment, coinfection with Hepatitis A,C,D viruses or HIV, Severe dysfunction of liver and kidney, pregnancy, breast feeding, refusing to give informed consent .

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **74**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Guilan University of Medical Sciences, Gastrointestinal and Liver Diseases Research Center

**Street address**

Gastrointestinal and liver disease research center, Sardar Jangal Ave, Razi hospital, Rasht

**City**

Rasht

**Postal code**

41448-95655

**Approval date**

2009-03-03, 1387/12/13

**Ethics committee reference number**

143

## Health conditions studied

### 1

**Description of health condition studied**

Chronic hepatitis B

**ICD-10 code**

B18.1

**ICD-10 code description**

Chronic viral hepatitis B without delta-agent

## Primary outcomes

### 1

**Description**

Response to treatment

**Timepoint**

24 week after treatment

**Method of measurement**

HBV-DNA<200copies/ml measure with PCR

### 2

**Description**

Response to treatment

**Timepoint**

24 week after treatment

**Method of measurement**

normal level of ALT measure with Biochemical

## Secondary outcomes

### 1

**Description**

Adverse effects

**Timepoint**

monthly

**Method of measurement**

Clinical evaluation and lab tests

## Intervention groups

### 1

**Description**

180 µg/wk Pegylated Interferon alfa-2a plus 10 mg Adefovir for 48 week

**Category**

Treatment - Drugs

### 2

**Description**

180 µg/wk Pegylated Interferon alfa-2a and placebo for 48 week

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Guilan University, Gastrointestinal and Liver Diseases Research Center
**Full name of responsible person**
Dr.Fariborz Mansour Ghanaei
**Street address**
Razi hospital, Sardar Jangal Ave.
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**2**

**Recruitment center**
**Name of recruitment center**
Mashhad University, Gastrointestinal and Liver Diseases Research Center
**Full name of responsible person**
Dr. Vosoghinia
**Street address**
**City**
Mashhad

**3**

**Recruitment center**
**Name of recruitment center**
Ghom University of Medical Sciences
**Full name of responsible person**
Dr. Mohamad Reza Ghadir
**Street address**
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Guilan University of Medical Sciences
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Farahnaz Joukar
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Razi Hospital, Sardare Jangal Ave.
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Rasht
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Guilan 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

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## Person responsible for updating data

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## 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*