

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Immunomodulator 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

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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 immunomodulator 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.

City

Rasht

2

Recruitment center

Name of recruitment center

Mashhad University, Gastrointestinal and Liver
Diseases Research Center

Full name of responsible person

Dr. Vosoghnia

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

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Farahnaz Joukar

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Razi Hospital, Sardare Jangal Ave.

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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

Contact

Name of organization / entity

Gastrointestinal and liver disease research center

Full name of responsible person

Farahnaz Joukar

Position

Assistant of Gastrointestinal and Liver Diseasea
Research Center

Other areas of specialty/work

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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