

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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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Phone

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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. 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**City**

Ghom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Farahnaz Joukar

Street address

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 Disease
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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