Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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)

Phone

+98 13 1553 5116

Email address

info@gldrc.org

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.
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.
City
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

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
Street address
Razi hospital, Sardar Jangal Ave.
City
Rasht
Postal code
41448-95655
Phone
+98 13 1553 5116
Fax
+98 13 1553 4951
Email
f_jokar@gums.ac.ir
Web page address
www.gldrc.org

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gastrointestinal and liver disease research center
Full name of responsible person
Dr.Fariborz Mansour Ghanaei
Position
Professor of Internal Medicine & Gastroenterology
Other areas of specialty/work
Street address
Razi Hospital, Sardare Jangal Ave.
City
Rasht
Postal code
41448-95655
Phone
+98 13 1553 5116
Fax
+98 13 1553 4951
Email
ghanaei@gums.ac.ir
Web page address
www.gldrc.org

Person responsible for updating data

Contact
Name of organization / entity
Gastrointestinal and liver disease research center

Full name of responsible person
Dr.Helia Valaee Barhagh
Position
Researcher
Other areas of specialty/work
Street address
Razi hospital, Sardar Jangal Ave.
City
Rasht
Postal code
41448-95655
Phone
+98 13 1553 5116
Fax
+98 13 1553 4951
Email
h.barhagh79@gmail.com
Web page address
www.gldrc.org

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