

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of Combination Peg interferon -alpha to Tenofovir versus each one of the treatment modalities alone on Patients with HBeAg-negative: A randomized clinical trial

Protocol summary

Study aim

The effect of Combination Peg interferon -alpha to Tenofovir versus each one of the treatment modalities alone on Patients with HBeAg-negative

Design

In this randomized clinical trial 75 patients with HBeAg-negative and treatment-naive In the third phase were randomly assigned into the three treatment groups.

Settings and conduct

All Patients with diagnosis of definitive chronic Hepatitis B who referred to Hepatitis Clinic of Rasoul-e-Akram Hospital were included.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with the age of 18-65 years and negative Hepatitis B e antigen at baseline, quantifiable serum hepatitis B viral DNA load > 2000 IU/ml; at least six months from the initial diagnosis; and those with no history of receiving an antiviral drug for treating hepatitis. Exclusion criteria: hepatitis C, D and HIV Viruses co-infection; Dialysis patients with renal impairment, severe liver diseases, history of previous hepatitis B treatment (for at least 30 days), other liver comorbidities such as Autoimmune Hepatitis, Alcohol > 40gr/day for men and 20gr/day for women, Hepatocellular Carcinoma, uncompensated cirrhosis, hemoglobin < 10 g/dL, platelet count < 70,000/mm³, white cell count < 3,000/mm³ and a contraindication to treatment including the concurrent advanced disease (uncontrolled depression, psychosis, epilepsy, autoimmune diseases, poorly controlled hypertension, diabetes and heart failure).

Intervention groups

The study comprised of three different groups. Group A: Patients who received the coincided combination of tenofovir (300 mg/day) and Peg- IFN α (180 mcg/week). Group B: Patients who received only tenofovir (300 mg/day); and Group C: Peg- IFN α (180 mcg/kg/ week for

48 weeks.

Main outcome variables

normalization of ALT (ALT \leq 40 IU/L) and reduction HBV DNA load of <200 IU/mL at week 48.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181113041635N1**

Registration date: **2019-05-08, 1398/02/18**

Registration timing: **retrospective**

Last update: **2019-05-08, 1398/02/18**

Update count: **0**

Registration date

2019-05-08, 1398/02/18

Registrant information

Name

Shahram Agah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 4790

Email address

agah.sh@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

2015-09-23, 1394/07/01

Actual recruitment end date

2018-12-31, 1397/10/10

Trial completion date

2018-12-31, 1397/10/10

Scientific title

The effect of Combination Peg interferon -alpha to Tenofovir versus each one of the treatment modalities alone on Patients with HBeAg-negative: A randomized clinical trial

Public title

The effect of Combination Peg interferon -alpha to Tenofovir versus each one of the treatment modalities alone on Patients with HBeAg-negative: A randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with the age of 18-65 years Negative Hepatitis B e antigen at baseline Quantifiable serum hepatitis B viral DNA load > 2000 IU/ml At least six months from the initial diagnosis Those with no history of receiving an antiviral drug

Exclusion criteria:

Hepatitis C, D and HIV Viruses co-infection Dialysis patients with renal impairment Severe liver diseases History of previous hepatitis B treatment (for at least 30 days) Other liver comorbidities such as Autoimmune Hepatitis Hepatocellular Carcinoma, uncompensated cirrhosis

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: **60**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Using statistical software

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran National Science Foundation

Street address

Amir Abad 5th St.

City

Tehran

Province

Tehran

Postal code

1439634665

Approval date

2012-07-07, 1391/04/17

Ethics committee reference number

۹۰۰۰۷۷۴۳

Health conditions studied

1

Description of health condition studied

Hepatitis B

ICD-10 code

B18.1

ICD-10 code description

Chronic viral hepatitis B without delta-agent

Primary outcomes

1

Description

The final end-points were rate of HBV DNA loss < 20 IU/ml at week 48.

Timepoint

HBV DNA load Will be measured. in the Twelve, Twenty-four, thirty-six and 48 weeks for all patients.

Method of measurement

by using of Cobas TaqMan polymerase chain reaction (Roche Diagnostics Basel, Switzerland) by Keyvan Virology Specialty Laboratory (KVSL).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A: Patients who received the coincided combination of tenofovir (300 mg/day) and Peg- IFN α (180 mcg/week) for 48 weeks.

Category

Treatment - Drugs

2

Description

Intervention group: Group B: Patients who received only tenofovir (300 mg/day) for 48 weeks

Category

Treatment - Drugs

3

Description

Intervention group: Group C: Peg- IFN α (180 mcg/kg/ week) for 48 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hepatitis Clinic of Rasoul-e-Akram Hospital

Full name of responsible person

Mansour Bahardoust

Street address

Rasoul Akram Hospital, Nyaiesh Ave., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice presidency for sciences and technology , Iran national sciences foundation

Full name of responsible person

shahram Agah

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Tehran, Amir Abad, 5th St

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medicine@insf.org

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

vice presidency for sciences and technology , Iran national sciences foundation

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

2

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malakuti - Vice Chancellor for research of Iran University of Medical Sciences

Street address

Vice Chancellor for research of Iran University of Medical Sciences, next to Milad Tower, Shahid Hemmat Highway, Tehran, Iran

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Email

research@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Shahram Agah

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data**Contact****Name of organization / entity****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Not applicable

When the data will become available and for how long

1400

To whom data/document is available

researchers

Under which criteria data/document could be used

treatment type

From where data/document is obtainable

Colorectal Research Center

What processes are involved for a request to access data/document

request

Comments