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- IFNα (180 mcg/week). Group B: Patients who received only tenofovir (300 mg/day); and Group C: Peg- IFNα (180 mcg/kg/ week for 48 weeks.

Main outcome variables

normalization of ALT (ALT ≤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- IFNα (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- IFNα (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
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 6655 4790
Email
agah.sh@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
vice presidency for siences and technology , Iran national silences foundation
Full name of responsible person
shahram Agah
Street address
Tehran, Amir Abad, 5th St
City
Tehran
Province
Tehran
Postal code
1439634665
Phone
+98 21 8216 1000
Email
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 siences and technology , Iran national silences 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
City
tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
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
Street address
Rasoul Akram Hospital, Nyaiesh Ave.
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6655 4790
Email
agah.sh@iums.ac.ir

Person responsible for scientific 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
Street address
Rasoul Akram Hospital, Nyaiesh Ave.
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6655 4790
Email
agah.sh@iums.ac.ir

Person responsible for updating data

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
Street address
Rasoul Akram Hospital, Nyaiesh Ave.
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6655 4790
Email
agah.sh@iums.ac.ir

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