

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Short term Efficacy and Safety of Alpha Interferon -2b (Pasture Made) plus Ribavirin for Treatment of the Patients with Chronic Hepatitis C

Protocol summary

Summary

Aim: to assess the safety and efficacy of regimen of Alpha Interferon -2b (Pasture Made) plus Ribavirin in a number of Iranian patients with chronic hepatitis C. Inclusion Criteria: older than 18 years, HCV RNA in serum on polymerase-chain-reaction (PCR) assay Exclusion Criteria: decompensated cirrhosis, autoimmune disease, evidence of cancer on ultrasonography or a high serum alfa-fetoprotein concentration, co-infection with HBV or HIV, neutropenia (neutrophil count <1500 cells/mm³), thrombocytopenia (platelet count <90,000 cells/mm³), anemia (hemoglobin level <12 gr/dl for women and <13 gr/dl for men), creatinine concentration more than 1.5 times the upper limit of normal range, organ transplantation, neoplastic disease, severe cardiac or chronic pulmonary disease, poorly controlled psychiatric disorder, seizure disorder, retinopathy, active drug or alcohol abuse, pregnancy in patient or spouse or unwillingness to use contraception Sample size: 40 patients Intervention: Patients assigned to receive subcutaneous treatment with Alpha Interferon -2b (Pasture made) Every other day plus oral treatment with Ribavirin 10-15 mg/kg per day. Primary outcome: rapid virologic response (RVR)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812123307N4**
Registration date: **2010-03-03, 1388/12/12**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-03-03, 1388/12/12

Registrant information

Name

Seyed Moayed Alavian

Name of organization / entity

BRCGL-THC

Country

Iran (Islamic Republic of)

Phone

+98 21 8126 2072

Email address

info@brcgl.ir

Recruitment status

Recruitment complete

Funding source

Pasteur Institute of Iran (IPI)

Expected recruitment start date

2010-04-01, 1389/01/12

Expected recruitment end date

2012-08-01, 1391/05/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Short term Efficacy and Safety of Alpha Interferon -2b (Pasture Made) plus Ribavirin for Treatment of the Patients with Chronic Hepatitis C

Public title

Short term Efficacy and Safety of Alpha Interferon -2b (Pasture Made) plus Ribavirin for Treatment of the Patients with Chronic Hepatitis C

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Impossibility for administration of peg-interferon according to recommendation of relevant

specialist, older than 18 years, HCV RNA in serum on polymerase-chain-reaction (PCR) assay Exclusion Criteria: decompensated cirrhosis, autoimmune disease, evidence of cancer on ultrasonography or a high serum alfa-fetoprotein concentration, co-infection with HBV or HIV, neutropenia (neutrophil count <1500 cells/mm³), thrombocytopenia (platelet count <90,000 cells/mm³), anemia (hemoglobin level <12 gr/dl for women and <13 gr/dl for men), creatinine concentration more than 1.5 times the upper limit of normal range, organ transplantation, neoplastic disease, severe cardiac or chronic pulmonary disease, poorly controlled psychiatric disorder, seizure disorder, retinopathy, active drug or alcohol abuse, pregnancy in patient or spouse or unwillingness to use contraception.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Baqyatallah University of Medical Sciences

Street address

Baqyatallah University of Medical Sciences, Mollasdra Ave., Vanak Squ

City

Tehran

Postal code**Approval date**

empty

Ethics committee reference number

5758

Health conditions studied**1****Description of health condition studied**

Chronic Hepatitis C

ICD-10 code

B18.2

ICD-10 code description

Chronic viral hepatitis C

Primary outcomes**1****Description**

rapid virologic response (RVR)

Timepoint

1 month after treatment initiation

Method of measurement

PCR

Secondary outcomes**1****Description**

sustained virologic response (SVR)

Timepoint

Every 3 months

Method of measurement

PCR

Intervention groups**1****Description**

Subcutaneous treatment with Alpha Interferon -2b (Pasture Made) Every other day plus oral treatment with ribavirin 10-15 mg/kg per day for 24 to 48 weeks according to the genotype of virus.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tehran Hepatitis Center

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pasteur Institute of Iran (IPI)

Full name of responsible person

Dr sayaed Moayed Alavian

Street address

NO. 69, Pasteur Ave., po code:13164

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Pasteur Institute of Iran (IPI)

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**

Baqiyatallah Research Center for Gastroenterology and Liver Diseases

Full name of responsible person

Mehrdad Nooranipour

Position

M.D

Other areas of specialty/work**Street address**

Ground Floor of Baqiyatallah Hospital, Baqiyatallah Medical University, Mollasdra Ave., Vanak Squ

City

Tehran

Postal code**Phone**

+98 21 8861 4523

Fax**Email**

manager@hepmon.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Baqiyatallah Research Center for Gastroenterology

and Liver Diseases

Full name of responsible person

Sayed Moayed Alavian

Position

M.D

Other areas of specialty/work**Street address**

Ground Floor of Baqiyatallah Hospital, Baqiyatallah Medical University, Mollasdra Ave., Vanak Squ

City

Tehran

Postal code**Phone**

+98 21 8861 4523

Fax**Email**

editor@hepmon.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Baqiyatallah Research Center for Gastroenterology and Liver Diseases

Full name of responsible person

Mostafa Shafiei

Position

M.D

Other areas of specialty/work**Street address**

Ground Floor of Baqiyatallah Hospital, Baqiyatallah Medical University, Mollasdra Ave., Vanak Squ

City

Tehran

Postal code**Phone**

+98 21 8861 4523

Fax**Email**

mostafa.gilani@gmail.com

Web page address

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