

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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/mm<sup>3</sup>), thrombocytopenia (platelet count <90,000 cells/mm<sup>3</sup>), 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/mm<sup>3</sup>), thrombocytopenia (platelet count <90,000 cells/mm<sup>3</sup>), 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

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manager@hepmon.ir

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### Person responsible for scientific inquiries

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### Person responsible for updating data

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mostafa.gilani@gmail.com

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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*