Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Email address
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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