Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

A comparison of vitB12 plus standard chronic HCV treatment with standard chronic HCV treatment on sustained virologic response rate

Protocol summary

Summary

This randomized clinical trial will be done on 74 chronic naive HCV patients at gastrointestinal clinic of Rasoul Akram Hospital.The patients are randomly enrolled to either of the two groups using a computer-generated randomization.37 patients receive (group A):Peg-IFNa2b 1.5 mg/kg/week subcutaneously and oral ribavirin ; according to body weight(1000 mg/day for weighing <75 kg, 1200 mg/day for weighing >75 kg in genotype 1 or 4 and a single ribavirin dose of 800 mg/day in genotype 2 or 3.37 patients receive (group A): Peg-IFNa2b 1.5 mg/kg/week subcutaneously and ribavirin ; according to body weight(1000 mg/day for weighing <75 kg, 1200 mg/day for weighing >75 kg in genotype 1 or 4 and a single ribavirin dose of 800 mg/day in genotype 2 or 3 plus vitamin B125000 microgram intramuscular injection every 4 weeks for the duration of the antiviral therapy.The randomisation lists are separately generated for difficult-to-treat genotypes (genotype 1 or 4) and easy-totreat genotypes (genotype 2 or 3) in order to balance the two treatment groups.All patients are sent for :CBC,ALT,AST,GAMMAGT,ALP,BILI(T&D),PT,ALB,CHOLESTEROL,ANTIHCVAb,HCV PCR&GENOTYP and fibroscan for steatosis and fibrosis scoring.Quantitative HCV-RNA PCR , ALT and AST levels are measured 4, 12,24, 48 and 72 weeks after the start of antiviral therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041720178N3**
Registration date: **2015-05-03, 1394/02/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-05-03, 1394/02/13

Registrant information

Name

Marjan Mokhtare

Name of organization / entity

Iran University of Medical sciences,Rasoul Akram Hospital,Colorectal Research Center

Country

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences,Rasoul Akram Hospital,Colorectal Research Center

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of vitB12 plus standard chronic HCV treatment with standard chronic HCV treatment on sustained virologic response rate

Public title

Efficacy of vitB12 plus standard chronic HCV treatment versus standard chronic HCV treatment on sustained virologic response rate

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:naive HCV hepatitis patients that refer to Rasoul Akram Hospital,Gastroenterology Clinic. Exclusion criteria:age<18 and age>70,previous treatment with interferon and/or ribavirin,concomitant causes of liver disease, such as HBV infection and autoimmune Hepatitis, alcohol user, HIV infection, hepatocellular carcinoma, decompensated cirrhosis, severe concurrent disease and contraindications to treatment including uncontrolled depression,psychosis, epilepsy, autoimmune diseases, poorlycontrolled hypertension, diabetes, heart failure and chronic obstructive pulmonary disease.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
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 University of Medical Sciences Ethics Committee
Street address
Iran University of Medical Sciences,West Shahid Hemmat Highway,Intersection of Chamran and Sheikh Fazlollah Noori,Tehran Iran
City
Tehran
Postal code
Approval date
2015-04-15, 1394/01/26
Ethics committee reference number
25592

Health conditions studied

1

Description of health condition studied
Chronic viral hepatitis C
ICD-10 code
B18.2
ICD-10 code description
Chronic viral hepatitis C

Primary outcomes

1

Description
Sustained virologic response rate
Timepoint
24 weeks after treatment completion
Method of measurement
Quantitative HCV-PCR

Secondary outcomes

1

Description
HCV genotype pattern
Timepoint
at the begining of treatment
Method of measurement
HCV genotyping

2

Description
Drug adverse effect rate
Timepoint
During treatment
Method of measurement
Data gathering sheet

3

Description
Non-responder rate
Timepoint
12 and 24 weeks after start treatment
Method of measurement
Quantitative HCV-PCR

4

Description
Rapid viral response rate
Timepoint
4 weeks after start treatment
Method of measurement
Quantitative HCV-PCR

5

Description
Complete early viral response rate
Timepoint
12 weeks after start treatment
Method of measurement
Quantitative HCV-PCR

6

Description
Dropout rate
Timepoint
During treatment
Method of measurement
Data gathering sheet

7

Description
liver steatosis and fibrosis rate
Timepoint
at first time before treatment
Method of measurement
liver fibroscan and/or biopsy

8

Description
Patient compliance rate
Timepoint
at the end of treatment
Method of measurement
Data gathering sheet

9

Description
The end-oftreatment viral response rate
Timepoint
at the end of treatment
Method of measurement
Quantitative HCV-PCR

10

Description
Virological breakthrough rate
Timepoint
During treatment
Method of measurement
Quantitative HCV-PCR

11

Description
Relapse rate
Timepoint
during 24 weeks after completing treatment
Method of measurement
Quantitative HCV-PCR

Intervention groups

1

Description
control:: Peg-IFNa2b 1.5 mg/kg/week subcutaneously and ribavirin ; according to body weight(1000 mg/day for weighing <75 kg, 1200 mg/day for weighing >75 kg in genotype 1 or 4 and a single ribavirin dose of 800 mg/day in genotype 2 or 3 .
Category
Treatment - Drugs

2

Description
Intervention: : Peg-IFNa2b 1.5 mg/kg/week subcutaneously and ribavirin ; according to body weight(1000 mg/day for weighing <75 kg, 1200 mg/day for weighing >75 kg in genotype 1 or 4 and a single ribavirin dose of 800 mg/day in genotype 2 or 3 plus vitamin B12 5000 microgram intramuscular injection every 4 weeks for the duration of the antiviral therapy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Colorectal Research Center, Rasoul Akram Hospital
Full name of responsible person
Marjan Mokhtare
Street address
Sattarkhan Street, Niayesh Street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences,Rasoul Akram Hospital,Colorectal Research Center
Full name of responsible person
Doctor Shahram Agah
Street address
Sattarkhan Street, Niayesh Street
City
Tehran
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,Rasoul Akram Hospital,Colorectal Research Center

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
Colorectal Research Center, Rasoul Akram Hospital
Full name of responsible person
Marjan Mokhtare
Position
Gastroenterologist and Hepatologist, Assistant professor
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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