

# 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-IFN $\alpha$ 2b 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 B): Peg-IFN $\alpha$ 2b 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. The randomisation lists are separately generated for difficult-to-treat genotypes (genotype 1 or 4) and easy-to-treat 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

Iran (Islamic Republic of)

###### Phone

+98 21 6652 2845

###### Email address

mokhtare.m@iums.ac.ir

##### 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 beginning 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-of-treatment 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***City**

Tehran

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marjanmokhtare@yahoo.com-  
mokhtaredr@gmail.com**Web page address****Person responsible for general inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Marjan Mokhtare

**Position**Gastroenterologist and Hepatologist, Assistant  
professor**Other areas of specialty/work****Street address**

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**Full name of responsible person**

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mokhtaredr@gmail.com**Web page address****Person responsible for scientific 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**Other areas of specialty/work****Street address**Colorectal Research Center, Rasoul Akram  
Hospital, Niayesh Street, Sattarkhan Street**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*