

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The effect of vitamin B12 supplementation to the standard therapeutic regimen on sustained viral response in genotype 1 chronic HCV infection

#### Protocol summary

##### Summary

**Objectives** The main objective of this study is to evaluate the impact of addition of vitamin B12 to the standard treatment regimen for hepatitis C genotype one. Design, setting and conduct In this study, all patients with chronic hepatitis C genotype 1 referred to hepatitis clinic will be enrolled after obtaining informed consent and exerting exclusion criteria. Patients are randomly assigned to two groups: one with standard therapy and other standard therapy with vitamin B-12. Permuted block randomization will be conducted by an independent personnel. To homogenize two groups randomization will be done based on primary viral levels (higher than IU / ML 600000 or less). Major exclusion criteria: age <18 or >70 year, HIV or HBV co-infection, concomitant severe disease or any contraindication to interferon and ribavirin taking. Major inclusion criteria: Patients between 18 and 70 year old, Lack of HIV or HBV co-infection, Lack of concomitant severe disease or any contraindication to interferon and ribavirin taking. **Intervention** Patients in the intervention group will receive standard regimen with a monthly dose of 5000 micrograms intramuscular vitamin B12 and patients in control group will only take the standard regimen without B12. **Main outcome measures** According to the clinic protocol all routine tests will be done as the standard schedule. At the end of the standard treatment, groups are compared in terms of sustained viral response as the primary outcome.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201508064226N3**

Registration date: **2015-09-20, 1394/06/29**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-09-20, 1394/06/29

##### Registrant information

###### Name

Gholam Reza Sivandzadeh

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1647 4316

###### Email address

ghsivand@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Gastroenterohepatology Research Center. Shiraz University of Medical Sciences

##### Expected recruitment start date

2015-08-23, 1394/06/01

##### Expected recruitment end date

2017-08-23, 1396/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of vitamin B12 supplementation to the standard therapeutic regimen on sustained viral response in genotype 1 chronic HCV infection

##### Public title

Vitamin B 12 in the treatment of chronic hepatitis C

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Exclusion criteria: age <18 or >70 year, previous treatment with interferon and ribavirin, concomitant causes of liver disease, such as hepatitis B virus infection, autoimmunity and alcohol abuse (>40 g/day for men and >20 g/day for women), HIV infection, hepatocellular carcinoma, decompensated cirrhosis, severe concurrent disease, contraindications to treatment. Inclusion criteria: age between 18 to 70 years, Lack of concomitant causes of liver disease, such as hepatitis B virus infection, autoimmunity and alcohol abuse (>40 g/day for men and >20 g/day for women), Lack of HIV infection, Lack of hepatocellular carcinoma, Lack of decompensated cirrhosis, Lack of severe concurrent disease.

### **Age**

From **18 years** old to **70 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **50**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

Permuted block randomization will be conducted by an independent personnel.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Shiraz University of Medical Sciences

##### **Street address**

Zand street, Namazi square,

##### **City**

Shiraz

##### **Postal code**

#### **Approval date**

2015-06-22, 1394/04/01

#### **Ethics committee reference number**

IR.SUMS.REC.1394.68

## **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**

Sustained Virologic Response

#### **Timepoint**

6 months after treatment course

#### **Method of measurement**

copy of virus in ml of serum

## **Secondary outcomes**

### **1**

#### **Description**

Serum viral load

#### **Timepoint**

baseline-3months-6months- end of treatment

#### **Method of measurement**

Copy of virus per milliliter

### **2**

#### **Description**

Liver enzymes

#### **Timepoint**

baseline-3months-6months- end of treatment- 6 months after treatment course

#### **Method of measurement**

miligram per deciliter of serum

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Monthly injection of 1000microg vitamin b12 produced by Osveh company for 12 months totally.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: Control group will only receive standard treatment

#### **Category**

N/A

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Hepatitis Clinic, Motahari Clinic

**Full name of responsible person**

Gholam Reza Sivandzadeh

**Street address**

Motahari Clinic, Namazi square, Zand street,

**City**

Shiraz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Shiraz University of Medical Sciences

**Full name of responsible person**

Seyyed Basir Hashemi

**Street address**

Namazi hospital, Namazi square

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Shiraz University of Medical Sciences

**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**

Gastroenterohepatology research center, Shiraz University of Medical Sciences

**Full name of responsible person**

Gholam Reza Sivandzadeh

**Position**

Internal Medicine Ward alumni

**Other areas of specialty/work**

**Street address**

Namazi hospital, Namazi hospital, Zand square

**City**

Shiraz

**Postal code**

7193711351

**Phone**

+98 71 3647 3236

**Fax**

**Email**

ghsivand@sums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Gastroenterohepatology center, Shiraz University of Medical Sciences

**Full name of responsible person**

Gholam Reza Sivandzadeh

**Position**

Gastroenterologist, MD

**Other areas of specialty/work**

**Street address**

Namazi hospital, Namazi square

**City**

Shiraz

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Gastroenterohepatology research center

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Gholam Reza Sivandzadeh

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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*