

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

### The effect of vitamin B12 supplementation on liver enzymes and viral load in nonresponding or early relapsing cases of chronic HCV hepatitis

#### Protocol summary

##### Summary

**Objectives** The main objective of this study is to evaluate the impact of vitamin B12 on the liver enzymes and viral load of chronic hepatitis C genotype 1. **Design, setting and conduct** In this study, thirty cases of chronic hepatitis C genotype 1 who had not responded to or relapsed after standard therapy will be enrolled after obtaining informed consent and exerting exclusion criteria. Patients are randomly assigned to two groups: one treated with vitamin B12 and other received no specific medication. Permuted block randomization will be conducted by an independent personnel. **Major exclusion criteria:** age <18 or >70 year, HIV or HBV co-infection, concomitant severe disease. **Major inclusion criteria:** Patients between 18 and 70 year old, Lack of HIV or HBV co-infection, Lack of concomitant severe disease. **Intervention** Patients in the intervention group will receive a monthly dose of 5000 micrograms intramuscular vitamin B12 for 3 successive months and patients in control group will not take any specific medication. **Main outcome measures** Serum viral load would be measured at the beginning, end of the first month, end of the treatment, and 3 months after end of treatment with vitamin B12 as the primary end points and would be compared with the control group equivalents.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201511274226N4**

Registration date: **2015-12-11, 1394/09/20**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-12-11, 1394/09/20

##### 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

2016-01-06, 1394/10/16

##### Expected recruitment end date

2016-06-20, 1395/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of vitamin B12 supplementation on liver enzymes and viral load in nonresponding or early relapsing cases of chronic HCV hepatitis

##### Public title

Vitamin B12 in chronic hepatitis C

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Exclusion criteria: age <18 or >70 year, 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 with vitamin B12. 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: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****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**

2015-08-02, 1394/05/11

**Ethics committee reference number**

IR.SUMS.REC.1394.80

**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**

serum viral load

**Timepoint**

before intervention, one month after intervention, end of intervention, 3 months after the end of intervention

**Method of measurement**

copy of virus in ml of serum

**Secondary outcomes****1****Description**

liver enzymes

**Timepoint**

before intervention, one month after intervention, end of intervention, 3 months after the end of intervention

**Method of measurement**

milligram per deciliter of serum

**Intervention groups****1****Description**

Intervention group: Monthly injection of 1000microgr vitamin b12 produced by Osveh company for 3 months totally.

**Category**

Treatment - Drugs

**2****Description**

Control group: Control group will not receive any medication

**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

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## 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

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## Person responsible for updating data

**Contact****Name of organization / entity**

Gastroenterohepatology research center

**Full name of responsible person**

Gholam Reza Sivandzadeh

**Position**

Internal medicine ward alumni

**Other areas of specialty/work****Street address**

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**Postal code**

7193711351

**Phone**

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**Fax****Email**

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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*