

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

Postal code

7193711351

Phone

+98 71 3647 3236

Fax

Email

ghsivand@sums.ac.ir

Web page address

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

Namazi hospital, Namazi square, Zand street

City

Shiraz

Postal code

7193711351

Phone

Fax

Email

ghsivand@sums.ac.ir

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