

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of adding vitamin D to standard HCV regimen(PEG-interferon plus ribaverin) on early virologic response(EVR)

Protocol summary

Summary

Objective: Evaluation of adding vitamin D to standard HCV regimen(PEG-interferon plus ribaverin) on early virologic response(EVR) Design: Randomized, not-blinded Setting and conduct: Sixty patients with untreated chronic hepatitis and positive HCV antibodies, referring to Ghaem and Emam Reza Specialized Clinics, were randomly allocated to 2 groups using stratification method. The groups are as follows: The intervention group: Thirty patients with hepatitis C, who received the standard treatment based on the PCR results and HCV genotype determination; they were also administered vitamin D. The control group: Thirty patients with hepatitis C, who received the standard treatment based on the PCR results and HCV genotype determination. The standard diet in genotype 1 or 4 includes peginterferon α 2a (180 mcg) together with (edible) ribavirin (800-1200 mg); the duration of the treatment was 48 weeks. The standard diet in genotype 2 and 3 includes peginterferon α 2a (180 mcg) together with (edible) ribavirin (800 mg), and the treatment takes 24 weeks. Major criteria to include in the study: The patients with hepatitis C who had not been under therapy were included in the study. Major criteria to exclude from the study: HIV patients; concurrent infection with hepatitis B and D; alcohol abuse; Wilson's disease; hemochromatosis; decompensated cirrhosis, child score>9; patients with hepatocellular carcinoma; previous hepatitis C treatment; chronic kidney disorder; using antiepileptic drugs; history of vitamin D consumption (in the control group); pregnancy or breastfeeding; and steroid consumption. Intervention: D vitamin, Weekly, 1600 Unit a day, for 8 to 12 weeks. Then monthly to the end of treatment. Primary outcome measure: D Vitamin and Calcium serum level, At the beginning of treatment and every three months to the end of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112915581N1**

Registration date: **2013-12-25, 1392/10/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-12-25, 1392/10/04

Registrant information

Name

Ladan Goshayeshi

Name of organization / entity

Emam Reza Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 1763 0105

Email address

goshayeshil911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-06-21, 1393/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of adding vitamin D to standard HCV regimen(PEG-interferon plus ribaverin) on early virologic response(EVR)

Public title

Dietary supplement in chronic hepatitis C treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Major criteria to include in the study: The patients with hepatitis C who had not been under therapy were included in the study. Major criteria to exclude from the study: HIV patients; concurrent infection with hepatitis B and D; alcohol abuse; Wilson's disease; hemochromatosis; decompensated cirrhosis, child score>9; patients with hepatocellular carcinoma; previous hepatitis C treatment; chronic kidney disorder; using antiepileptic drugs; history of vitamin D consumption (in the control group); pregnancy or breastfeeding; and steroid consumption.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 30

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

Ethics committee, Mashhad University of Medical Sciences

Street address

Vice chancellor for research, Mashhad University of Medical Sciences, Daneshgah Street, Ghoreishi Building, Mashhad

City

Mashhad

Postal code

91375-3316

Approval date

2013-08-16, 1392/05/25

Ethics committee reference number

911015

Health conditions studied

1

Description of health condition studied

Hepatitis C

ICD-10 code

B18.2

ICD-10 code description

Chronic viral hepatitis C

Primary outcomes

1

Description

D Vitamin serum level

Timepoint

At the beginning of treatment and every three months to the end of treatment

Method of measurement

Blood Sampling

2

Description

Calcium serum level

Timepoint

At the beginning of treatment and every three months to the end of treatment

Method of measurement

Blood Sampling

Secondary outcomes

1

Description

Quantification of HCV RNA

Timepoint

At weeks 4 and 12 during the treatment period for the assessment of RVR and EVR and at the end of treatment and 24 weeks after

Method of measurement

By Quantitative PCR

Intervention groups

1

Description

Intervention group: D vitamin, Weekly, 1600 Unit a day, for 8 to 12 weeks. Then monthly to the end of treatment.

Category

Treatment - Drugs

2

Description

Control group: Standard diet, The standard diet in genotype 1 or 4 includes peginterferon α 2a (180 mCg) together with (edible) ribavirin (800-1200 mg), the duration of the treatment is 48 weeks. The standard diet in genotype 2 and 3 includes peginterferon α 2a (180 mCg) together with (edible) ribavirin (800 mg), and the treatment takes 24 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Gastrointestinal Clinic

Full name of responsible person

Ladan Goshayeshi

Street address

Emem Reza Gastrointestinal Clinic, Ebnesina street, Mashhad

City

Mashhad

2

Recruitment center

Name of recruitment center

Ghaem Gastrointestinal Clinic

Full name of responsible person

Ladan Goshayeshi

Street address

Ghaem Gastrointestinal Clinic, Ghaem Hospital, Ahmadabad Street, Mashhad

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Ramezani

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Vice chancellor for research, Mashhad University of Medical Sciences, Daneshgah Street, Ghoreish Building, Mashhad

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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, Mashhad 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**

Emam Reza Hospital

Full name of responsible person

Ladan Goshayeshi

Position

Student Subspecialist of Gastroenterology

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Hasan Vosoughinia

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

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Position

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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