Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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 α2a (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 α2a (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)
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+98 51 1763 0105
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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, Danehgah 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 α2a (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 α2a (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
Mashhad

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

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

City
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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

Other areas of specialty/work

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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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Subspecialist of Gastroenterology

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Position
Student Subspecialist of Gastroenterology

Other areas of specialty/work

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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