

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

investigating the effects of Camel Milk Products on the laboratory markers in the patients with chronic hepatitis, genotype 2 & 3

Protocol summary

Summary

Study: investigating the effects of Camel Milk Products on the laboratory markers in the patients with chronic hepatitis, genotype 2 & 3 Design of study: RCT Study population: patients referred to a specialized clinic University Main inclusion criteria: age 18 to 70 years; the detection of serum HCV RNA by PCR Main exclusion criteria: decompensated cirrhosis; autoimmune diseases; cancer; lack of milk consumption with the dose; the patient withdrew from further participation in the plan; other genotypes Sample size: 40 patients Intervention group: Pegah interferon (Pgasys) at a dose of 180 mcg subcutaneously once weekly, and ribavirin dose of 800 to 1200 mg based on body weight orally daily and camel milk 250 cc daily in the morning and night for three months. Control group: Pegah interferon (Pgasys) at a dose of 180 mcg subcutaneously once weekly, and ribavirin dose of 800 to 1200 mg based on body weight orally for three months. C - Intervention Time: 3 months D - Primary outcome or consequences of the study: laboratory changes ALT, AST, and PCR

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112515533N1**

Registration date: **2014-08-20, 1393/05/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-20, 1393/05/29

Registrant information

Name

Mohammadreza Noras

Name of organization / entity

Faculty of Traditional Medicine

Country

Iran (Islamic Republic of)

Phone

+98 51 3855 2189

Email address

norasmr901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences Razi vaccine and Serum Research Institute of Mashhad

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

investigating the effects of Camel Milk Products on the laboratory markers in the patients with chronic hepatitis, genotype 2 & 3

Public title

Effect of camel milk on chronic hepatitis C

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: age 18 to 70 years; the detection of serum HCV RNA by PCR. exclusion criteria: Decompensated cirrhosis; autoimmune diseases; cancer; infected with HIV or HBV; neutropenia; thrombocytopenia; creatinine higher; organ transplant; severe heart disease; chronic

lung disease; uncontrolled psychiatric illness; epilepsy; diabetic retinopathy; active alcohol or addiction; pregnancy; anemia; non-compliance with the prescribed dosage milk; discourage patients from continuing to participate in the plan; other genotypes to participate in the plan; other genotypes

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

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

City

Mashhad

Postal code

Approval date

2014-07-16, 1393/04/25

Ethics committee reference number

research/922662/1/1063

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

Quantification of HCV RNA

Timepoint

One Month

Method of measurement

PCR

2

Description

level of ALT, AST

Timepoint

One Month

Method of measurement

unit /ml

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pegah interferon (Pegasys) at a dose of 180 mcg subcutaneously once weekly, and ribavirin dose of 800 to 1200 mg based on body weight orally daily and camel milk 250 cc daily in the morning and night for three months.

Category

Treatment - Drugs

2

Description

Control group: Pegah interferon (Pegasys) at a dose of 180 mcg subcutaneously once weekly, and ribavirin dose of 800 to 1200 mg based on body weight orally for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Gastrointestinal Clinic

Full name of responsible person

Seyyed Musa Al-Reza Hosseini

Street address

Ahmadabad Street, Ghaem Hospital, Ghaem Gastrointestinal Clinic, Mashhad

City

Mashhad

2

Recruitment center

Name of recruitment center

Faculty of Traditional Medicine Clinic

Full name of responsible person

Mohammadreza Noras

Street address

Faculty of Traditional Medicine

City

Mashhad

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mashhad University of Medical Sciences ,Vice
chancellor for research

Full name of responsible person

Said Islame

Street address

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

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences ,Vice chancellor
for research

Proportion provided by this source**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

2

Sponsor**Name of organization / entity**

Razi vaccine and Serum research Institue of Mashhd

Full name of responsible person

Said Zibae

Street address

Razi vaccine and Serum research Institue of Mashhd

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Razi vaccine and Serum research Institue of Mashhd

Proportion provided by this source**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**

Faculty of Traditional Medicine

Full name of responsible person

Mohammadreza Noras

Position

Phd student Traditional Medicine

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

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Department of Medicine Internal Clinic, Ghaem
Hospital

Full name of responsible person

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Position

Subspecialist of Gastroenterology

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Person responsible for updating data

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Full name of responsible person

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Fax**Email**

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