Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Direct-Acting Antiviral Regimens Effectiveness in Achieving Undetectable Viral Load in Chronic Hepatitis C Patients in Iran

Protocol summary

Summary

The aim of this study was to determine the effectiveness of regimens containing Direct Acting Antivirals (DAAs) in the treatment of chronic hepatitis C patients in Iran. Among the most critical inclusion criteria are the affirmation of infection with chronic hepatitis C by a detectable viral count and also unresponsiveness to previous interferon-based treatments or not being previously treated. Significant exclusion criteria include significant renal failure and advanced liver diseases. For 60 patients included in the study regarding the above-mentioned criteria, virus genotyping is carried out and they are treated with standardized protocols of DAAs made in Iran including daclatasvir, sofosbuvir and ledipasvir with or without interferon or ribavirin. The effectiveness of these regimens in the patients is assessed by determining their viral loads and alanine aminotransferase serum level and the data obtained is analyzed statistically.

General information

Acronym

DAAHepC

IRCT registration information

IRCT registration number: **IRCT2017020210417N6**
Registration date: **2017-03-05, 1395/12/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-05, 1395/12/15

Registrant information

Name

Babak Sayad

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 1823 3957

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Scieneces

Expected recruitment start date

2017-01-25, 1395/11/06

Expected recruitment end date

2018-01-26, 1396/11/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Direct-Acting Antiviral Regimens Effectiveness in Achieving Undetectable Viral Load in Chronic Hepatitis C Patients in Iran

Public title

The effect of generic drugs in treatment of chronic hepatitis C patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Being diagnosed with hepatitis C and having a detectable viral count; Having not received any medications yet or being unresponsive to previous interferon-based treatments; Providing a freely signed consent form to be treated with new generic medications. Exclusion criteria :Having a renal failure defined as eGFR < 30 mL/min; Having a very advanced

liver disease defined as MELD score > 20 or Child-Pugh score > 12; Heart rate < 50 beats/min; History of previous treatment failure with sofosbuvir-based regimen; History of taking amiodarone within the last 6 months; Not consenting to participate in the study.

Age
From **18 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
N/A

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
Kermanashah University of Medical Sciences

Street address
Kermanshah- Shahid Beheshti Bulevard- Building2- Vice – Chancellery of Research & Technology Affairs

City
Kermanshah

Postal code
6714673159

Approval date
2015-01-25, 1393/11/05

Ethics committee reference number
KUMS.REC.1395.630

Health conditions studied

1

Description of health condition studied
Chronic viral hepatitis C

ICD-10 code
B18.2

ICD-10 code description
Chronic viral hepatitis C

Primary outcomes

1

Description
Hepatitis C viral load

Timepoint
Beginig of treatment- one month after the begining of treatment- The end of treatment-Three months after the end of treatment

Method of measurement
Using Real Time PCR

2

Description
Hepatitis C virus genotype

Timepoint
at the beginning of treatment

Method of measurement
using gene sequencing

Secondary outcomes

1

Description
Alanin amino transferase (ALT)

Timepoint
At the beginning of treatment, then monthly for three months after the end of treatment

Method of measurement
Enzyme serum level

Intervention groups

1

Description
Sofosbuvir, tablet, 400mg, oral, once a day plus ribavirin, cap, 1000-1200 mg (per body weight), oral, daily plus IFN alpha 2b amp, 1.5 µg/Kg, daily, all for 3 months * This regimen is used for genotypes 1 and 3 of hepatitis C

Category
Treatment - Drugs

2

Description
Ledipasvir/sofosbuvir, tablet, 90/400 mg, oral, once a day, all for 3 months * In patients with cirrhosis ribavirin cap, 100-1200 mg daily is added to the above regimen ** This regimen is used for genotype 1 of hepatitis C

Category
Treatment - Drugs

3

Description
Daclatasvir, tablet, 60 mg, oral, once a day plus sofosbuvir, tablet, 400 mg, oral, once a day, all for 3 months * In patients with cirrhosis ribavirin cap,

100-1200 mg daily is added to the above regimen ** This regimen is used for genotype 3 of hepatitis C

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Liver Disease Research Center and relate clinic

Full name of responsible person

Dr.Babak Sayad

Street address

Krmanshah- Imam Reza Hospital- third floor-Liver Disease Research Center

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Kurosh Hamzehee

Street address

Kermanshah- Shahid Beheshti Bulevard- Building2- Vice – Chancellery of Research & Technology Affairs

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Fatemeh Norooznezhad

Position

Msc of medical immunology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Babak Sayad

Position

associate professor of infectious disease

Other areas of specialty/work

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Full name of responsible person

Fatemeh Norooznezhad

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