Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Compare the response to treatment in patients with newly diagnosed chronic hepatitis C (genotype I) and patients without any response to previous treatments , with combination of sofosbuvir-daklatsvir

Protocol summary

Summary

(1) The aim of this study was to compare the response to treatment in patients with newly diagnosed administration drug sovodak chronic hepatitis C genotype and patients with a previous treatment failure. (2)In this study, an experimental clinical trial carried out, (3) patients chronic hepatitis C infections with genotype one who refer Gastroenterology Clinics of Medical Sciences, 25 of people who ribavirin and interferon already had been in the first group and The 25 people who were newly diagnosed and had no previous treatment were selected in the second group. The two groups were matched for age, sex and diseases. (4) Inclusion criteria for this study, patients with HCV genotype HCV RNA in a headline above or positive and people who have detectable HCV RNA titers after previous treatment failure and relapse. Exclusion criteria from the study, those who sovodak therapy to stop for any reason, People infected with virus (HIV) simultaneously, chronic liver disease who are reason other than HCV. (5) Patients with drug therapy, Sofosbuvir daily oral dose of 400 mg and a dose of 60 mg daily Daklinza oral pharmaceutical composition sovodak for 12 weeks and (6) The results of treatment using HCV RNA at weeks 24,12,4 title will be monitored to determine response to therapy in each patient and compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702016388N7**
Registration date: **2017-04-08, 1396/01/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-08, 1396/01/19

Registrant information

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Mohamadhossein Somi
Name of organization / entity
Tabriz University of Medical Science
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Tabriz University of Medical Science

Expected recruitment start date

2016-11-12, 1395/08/22

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the response to treatment in patients with newly diagnosed chronic hepatitis C (genotype I) and patients without any response to previous treatments , with combination of sofosbuvir-daklatsvir

Public title

Response to treatment in patients with chronic hepatitis C genotype and drug sovodak newly diagnosed patients with previous treatment failure

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: People with HCV genotype HCV RNA in a headline above or positive؛ People who have detectable HCV RNA titers after previous treatment failure and relapse patients. Exclusion criteria: People who sovodak therapy to stop for any reason؛ People infected with virus (HIV) concurrently؛ There is no reason other than HCV patients with chronic hepatitis؛ People with hepatitis B concurrently؛ People who have undergone liver transplantation recently؛ People who have low life expectancy؛ There is no assurance that the cut intravenous drug users inject drugs؛ Patients who received Amiodarone in the last 6 months؛ Women who are pregnant or plan to become pregnant or are breastfeeding؛ Those who have allergies to Lactose (sovodak with Lactose).

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

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
Ethics Committee of Tabriz University of Medical Sciences

Street address
Central bulding of medical science university, St. Golgasht, St. Azadi ,Tabriz

City
Tabriz

Postal code

Approval date
2016-11-09, 1395/08/19

Ethics committee reference number
IR.tbzmed.ac.ir.1395.871

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
Hepatitis C RNA

Timepoint
Baseline, 4 weeks after treatment, 12 weeks after treatment, 24 weeks after treatment

Method of measurement
Test

Secondary outcomes

1

Description
Liver Echogenicity

Timepoint
Baseline, 4 weeks after treatment, 12 weeks after treatment, 24 weeks after treatment

Method of measurement
paraclinical tests

2

Description
Albumin

Timepoint
Baseline, 4 weeks after treatment, 12 weeks after treatment, 24 weeks after treatment

Method of measurement
Test

3

Description
Portal vein diameter

Timepoint
Baseline, 4 weeks after treatment, 12 weeks after treatment, 24 weeks after treatment

Method of measurement
Sonography

4

Description

Splenic vein diameter

Timepoint

Baseline, 4 weeks after treatment, 12 weeks after treatment, 24 weeks after treatment

Method of measurement

Sonography

5

Description

Spleen size

Timepoint

Baseline, 4 weeks after treatment, 12 weeks after treatment, 24 weeks after treatment

Method of measurement

Sonography

6

Description

INR

Timepoint

Baseline, 4 weeks after treatment, 12 weeks after treatment, 24 weeks after treatment

Method of measurement

Test

Intervention groups

1

Description

In the intervention group, patients with hepatitis C who were treated with other drugs and were facing defeat, Drug treatment, Sofosbuvir daily at a dose of 400 mg daily oral doses of 60 mg Daklinza oral pharmaceutical composition in a single pill called sovodak will receive for 12 weeks.

Category

Treatment - Drugs

2

Description

In the control group of patients with hepatitis C who have not previously undergone any treatment, Drug treatment, Sofosbuvir daily at a dose of 400 mg daily oral doses of 60 mg Daklinza oral pharmaceutical composition in a single pill called sovodak will receive for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences, Imam Reza Hospital

Full name of responsible person

Dr. Hosein Mehdipour

Street address

Endoscopy ward, First floor, Imam Reza Hospital, St. Golgasht, St.Azadi, Tabriz, East Azarbaijan

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Vice chancellor for Research of Tabriz University of Medical Sciences,Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

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 of Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hosein Somi

Position

Gastroentrology and hepatology/ Professor

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