

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Aug 2026

Comparative assessment of the efficacy and safety of add ontreatment with “Sofosbuvir plus Velpatasvir” to “standard of care therapeutic regimen” in patients with COVID-19

Protocol summary

Study aim

Comparison of the effectiveness and safety of the addition of Sofosbuvir plus Velpatasvir to standard treatment regimens in patients with COVID-19

Design

This study is one blinded clinical trial. The study population will be all patients infected with COVID-19 admitted to Golestan hospital of Kermanshah. 80 eligible patients will be selected conveniently and randomly assigned to two intervention groups.

Settings and conduct

The study, which will be conducted at Golestan Hospital of Kermanshah, is one-blinded one that participants are unaware of the type of treatment they receive. At the beginning of the study, the patient's clinical status is recorded in a checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years; Absolute lymphocyte count $<1100 / \text{ML}$ or $\text{SaO}_2 < 93$ Exclusion criteria: Pregnancy or breast-feeding The physician's decision that the trial is not in the patient's interest Any circumstances that do not allow the treatment protocol to be followed easily A history of severe liver disease including cirrhosis or ALT or AST levels more than five times normal Drugs that are contraindicated with standard treatment or Sofosbuvir-Velpatasvir and cannot be discontinued History of untreated HIV infection or hepatitis C

Intervention groups

The intervention group in addition to 400 mg of hydroxychloroquine and 100 to 400 mg of Lupinavir-ritonavir at a time, will receive 100 to 400 mg of Sofosbuvir-Velpatasvir for 10 days. The control group will receive 400 mg of hydroxychloroquine and 100 to 400 mg of lupinavir-ritonavir for 10 days at a time.

Main outcome variables

Clinical status

General information

Reason for update

Edite spelling in the title

Acronym

SOVECOD

IRCT registration information

IRCT registration number: **IRCT20130812014333N145**

Registration date: **2020-03-30, 1399/01/11**

Registration timing: **prospective**

Last update: **2020-04-07, 1399/01/19**

Update count: **2**

Registration date

2020-03-30, 1399/01/11

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

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fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2020-07-10, 1399/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative assessment of the efficacy and safety of add ontreatment with “Sofosbuvir plus Velpatasvir” to “standard of care therapeutic regimen” in patients with COVID-19

Public title
Comparative assessment of the efficacy and safety of add ontreatment with “Sofosbuvir standard of care therapeutic regimenVelpatasvir” to “standard of caretherapeutic regimen” in patients with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Absolute lymphocyte count <1100 / ML or SaO2 <93
Exclusion criteria:
Pregnancy or breast-feeding The physician's decision that the trial is not in the patient's interest Any circumstances that do not allow to follow the treatment protocol easily A history of severe liver disease including cirrhosis or ALT or AST levels more than fives times normal Drugs that are contraindicated with standard treatment or Sofosbuvir-Velpatasvir and cannot be discontinued History of untreated HIV infection or hepatitis C

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
• Participant

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the random number table, patients are divided into two groups of 40. Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the intervention group and patients whose last digit is 1,3,5, 7, 9 will be assigned to the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, patients will be kept blind to the type of treatment.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-03-03, 1398/12/13

Ethics committee reference number

lr.kums.rec.1399.044

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19 disease

Primary outcomes

1

Description

Clinical status

Timepoint

Beginning of the study, 10 days later, or discharge time

Method of measurement

By a doctor

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group in addition to standard treatment (400 mg of hydroxychloroquine and 100 to 400 mg of

Lupinavir-ritonavir at a time), will receive 100 to 400 mg of Sofosbuvir-Velpatasvir for 10 days.

Category

Treatment - Drugs

2

Description

The control group will receive standard treatment including 400 mg of hydroxychloroquine and 100 to 400 mg of lupinavir-ritonavir for 10 days at a time.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Dr. Babak Sayad

Street address

Golestan Hospital, Parastar Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

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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

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

Position

Member of Kermanshah University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Person responsible for scientific inquiries

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Name of organization / entity

Kermanshah University of Medical Sciences

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Position

Member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

4 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

Send E-mail to the responsible for the update to get the documentation

What processes are involved for a request to access data/document

Documentation will be emailed within a 45-day timeframe

Comments