Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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 / 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 the treatment protocol to be followed 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

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
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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

Ir.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
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Full name of responsible person
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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
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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 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