

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Aug 2026

Comparative assessment of the efficacy and safety of add-on treatment with “Sofosbuvir-Daclatasvir”, “Lithium”, and “Trifluoprazine” to “standard of care in three groups of patients with COVID-19

Protocol summary

Study aim

Comparative assessment of the efficacy and safety of add-on treatment with “Sofosbuvir-Daclatasvir”, “Lithium”, and “Trifluoprazine” to “standard of care in three groups of patients with COVID-19

Design

This study is a single 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 four intervention groups

Settings and conduct

The study, which will be conducted at Golestan Hospital of Kermanshah, is single blinded 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; A history of known allergies to Sofosbuvir-Velp, Trifluoperazine, Lithium, and Trihexyphenidyl; Drugs that their concomitant use with standard treatment or Sofosbuvir-Velpatasvir, Trifluoperazine, Lithium, and Trihexyphenidyl are contraindicated and can not be discontinued

Intervention groups

The first group will receive the standard treatment consisted of 200 mg Tab Hydroxychloroquine 2 times every 12 hours on the first day and then one every 12 hours up to 10 days). The second group will receive 60 to 400 mg daily of Tab Sofosbuvir-Daclatasvir for 10 days with standard treatment The third group will receive 300 mg Tab Lithium every 8 hours for 10 days with standard treatment. The fourth group will receive 5 mg Tab Trifluoprazine every 8 hours and 2 mg Tab Trihexyphenidyl every 8 hours with standard treatment

Main outcome variables

Hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N147**

Registration date: **2020-04-22, 1399/02/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-12, 1399/02/23**

Update count: **1**

Registration date

2020-04-22, 1399/02/03

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2020-06-09, 1399/03/20

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-on treatment with "Sofosbuvir-Daclatasvir", "Lithium", and "Trifluoprazine" to "standard of care in three groups of patients with COVID-19"

Public title

Comparative assessment of the efficacy and safety of add-on treatment with "Sofosbuvir-Daclatasvir", "Lithium", and "Trifluoprazine" to "standard of care in three groups of 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 the treatment protocol to be followed easily A history of known allergies to Sofosbuvir-Velp, Trifluoprazine, Lithium and Trihexyphenidyl Drugs that their concomitant use with standard treatment or Sofosbuvir-Velpatasvir, Trifluoprazine, Lithium, and Trihexyphenidyl are contraindicated and can not be discontinued.

AgeFrom **18 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant

Sample sizeTarget sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

The number of 1 to 80 is written on the cards and will put it in the envelope. Numbers 1-20 are assigned to the first intervention group, numbers 21-40 are assigned to the second intervention group, numbers 41-60 are assigned to the third intervention group, and numbers 61-80 are 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. This means that patients are aware of their participation in the study, but they are blind to the type and dosage of the medication they receive and are unaware of the allocation of study groups. Also, due to the fact that outpatients will be considered in this study, and patients separately will come to receive the

medication, they will be kept blind about the shape, size, and color of the medication.

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

2020-04-11, 1399/01/23

Ethics committee reference number

IR.KUMS.REC.1399.063

Health conditions studied**1****Description of health condition studied**

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes**1****Description**

Not need hospitalization, feels well, and is able to perform normal activities

Timepoint

On days 3, 5 and 10 of treatment

Method of measurement

Based on clinical examination

2**Description**

Not need hospitalization, feels ill but is able to perform

normal activities

Timepoint

On days 3, 5 and 10 of treatment

Method of measurement

Based on clinical examination

3**Description**

Not need hospitalization, feels ill and isn't able to perform normal activities

Timepoint

On days 3, 5 and 10 of treatment

Method of measurement

Based on clinical examination

4**Description**

Need hospitalization, feels ill and isn't able to perform normal activities

Timepoint

On days 3, 5 and 10 of treatment

Method of measurement

Based on clinical examination

Secondary outcomes

empty

Intervention groups**1****Description**

The first group will receive the standard treatment consisted of 200 mg Tab Hydroxychloroquine 2 times every 12 hours on the first day and then one every 12 hours up to 10 days).

Category

Treatment - Drugs

2**Description**

The second group will receive 60 to 400 mg daily of Tab Sofosbuvir-Daclatasvir for 10 days with standard treatment (200 mg Tab Hydroxychloroquine 2 times every 12 hours on the first day and then one every 12 hours up to 10 days)

Category

Treatment - Drugs

3**Description**

The third group will receive 300 mg Tab Lithium every 8 hours for 10 days with standard treatment (200 mg Tab Hydroxychloroquine 2 times every 12 hours on the first day and then one every 12 hours up to 10 days)

Category

Treatment - Drugs

4**Description**

The fourth group will receive 5 mg Tab Trifluoprazine every 8 hours and 2 mg Tab Trihexyphenidyl every 8 hours with standard treatment (200 mg Tab Hydroxychloroquine 2 times every 12 hours on the first day and then one every 12 hours up to 10 days)

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

City

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6715847141

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Email

babaksayad@kums.ac.ir

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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fnajafi@kums.ac.ir

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. Babak Sayad
Position
Faculty member of Kermanshah University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
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Person responsible for scientific inquiries

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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Other areas of specialty/work
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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

3 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 15-day timeframe

Comments