Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparative assessment of the efficacy and safety of addon 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 addon 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 / ML or SaO2 <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)

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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 addon 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 addon 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.
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
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

Kermanshah

Province

Kermanshah

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6715847141

Phone

+98 83 3427 6306

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

Street address

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

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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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Emam Reza Hospital, Parastar Boulevard

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Person responsible for scientific inquiries

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Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
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Position
Faculty member of Kermanshah University of Medical Sciences

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Dr. Reza Khodarahmi

Position
Faculty member of Kermanshah University of Medical Sciences

Latest degree
Specialist

Other areas of specialty/work
Biochemistry

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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