

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of the effectiveness of Sovodak (sofosbuvir + Daklatasvir) and Keltra treatment regimens in patients with COVID-19: a randomized single-blind study

Protocol summary

Study aim

If the difference or greater effect of chloroquine + Sovodak is confirmed compared to the chloroquine + culture diet, the chloroquine + Sovodak diet regimen can be used as an alternative regimen or even treatment. Primary used in patients with coronary infection.

Design

The study is a phase two, single-blind parallel clinical trial in which in each group 150 patients with a definite diagnosis of hospitalized coronary infection will be randomly assigned to two treatment groups in a ratio of 1: 1, chloroquine + treatment group Sovodak vs. Chloroquine + Keltra group therapy.

Settings and conduct

Phased double and single blind clinical trial study, in each group of 150 patients with a definitive diagnosis of corona virus infection admitted to Firoozgar and Rasoul Akram hospitals, will be randomly assigned to two treatment groups (chloroquine + Sovodak Vs. chloroquine + Kaletra group therapy). Patients and clinical staff in this study are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive diagnosis of Covid-19 Age older than or equal to 18 years Inpatients Exclusion criteria: Pregnant women Breastfeeding women Patients who need treatment with four drugs from the beginning People with decreased level of consciousness Blood pressure less than 60/90 mm Hg Respiratory rate above 24 hypoxia Reduction of saturation less than 90% Patients with various organ failure Patients required mechanical ventilation at the time of admission

Intervention groups

Patients with a definitive diagnosis of Corona virus infection admitted to Firoozgar and Rasoul Akram hospitals will be randomly assigned to two treatment groups (n-150 in each group) in a 1: 1 ratio chloroquine + Sovodak treatment group in Vs. chloroquine + Kaletra

group therapy.

Main outcome variables

Mortality rate; Duration of hospitalization; Need to be admitted to the ICU

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200328046885N1**

Registration date: **2020-10-12, 1399/07/21**

Registration timing: **retrospective**

Last update: **2020-10-12, 1399/07/21**

Update count: **0**

Registration date

2020-10-12, 1399/07/21

Registrant information

Name

Mahin Jamshidi Makiani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8893 7383

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-19, 1399/04/29

Expected recruitment end date

2020-10-11, 1399/07/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of Sovodak (sofosbuvir + Daklatasvir) and Kaletra treatment regimens in patients with COVID-19: a randomized single-blind study

Public title
Comparison of the effectiveness of two treatment regimens in patients with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of Covid-19 Inpatients Age older than or equal to 18 years
Exclusion criteria:
Pregnant women Breastfeeding women People with decreased level of consciousness Blood pressure less than 60/90 mm Hg Respiratory rate above 24 hypoxia Reduction of saturation less than 90% Patients with various organ failure Patients required mechanical ventilation at the time of admission

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description
How patients are randomized will be classified as randomization blocks. Patients who need hospitalization are divided into four categories based on SpO2 and high-risk groups at the beginning of the visit, including patients in the high-risk group with SaO2 below 93%, patients in the high-risk group with high or equal SaO2 93%, patients in the group Low risk with SaO2 below 93% and finally patients in the low risk group with high SaO2 or equal to 93% will be divided. High-risk criteria include age over 60, with underlying disease such as immunodeficiency, diabetes, cardiovascular disease, obstructive pulmonary disease, malignancies, immunosuppressive patients, patients undergoing chemotherapy, chronic liver disease including cirrhosis and chronic disease Kidney will be considered. In each floor, blocks of size 4 are considered so that assuming the drug combination of chloroquine + Sovodak (sofosbuvir + Daklatasvir) as drug combination A and drug combination chloroquine + Kaletra as B, permutations of blocks in the form of AABB, ABAB, BBAA

, BABA, ABBA, and BAAB will be produced. The sequence of blocks is randomly determined and patients in all four classes are named, thus depending on the time of referral will be placed in these blocks in order. It should be noted that the preparation of blocks and the placement of patients in blocks (assignment of patients to treatment groups) will be done by a third party who is not directly involved in the treatment of patients. Medications will also be prescribed by the clinical staff (assistants of the relevant departments) who are not involved in conducting this study.

Blinding (investigator's opinion)

Single blinded

Blinding description

Medications will also be prescribed by the clinical staff (assistants of the relevant departments) who are not involved in conducting this study. And trying to be a double-blind experiment. Treatment regimen in group A. Hydroxychloroquine phosphate 400 mg single dose + lopinavir / ritonavir 400/100 combination twice daily for at least 5 days Treatment regimen in group B. Hydroxychloroquine phosphate 400 mg every 12 hours for the first day and then 200 mg every 12 hours for 5 to 7 days + Sovodak (sofosbuvir + Daklatasvir) once a day (60/400 mg) for at least 5 to 7 days It should be noted that each treatment regimen for each patient will be placed in separate envelopes with labels known only to the prescriber (a third party who will be selected by a medical staff that is not directly involved in the study). In order to blind the contents of the tablets Sovodak (sofosbuvir + Daklatasvir) and Kaletra, in coordination with a hospital pharmacist, will be placed inside the same capsules whose contents have been emptied.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, next to Milad Tower, Hemat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-07-19, 1399/04/29

Ethics committee reference number

IR.IUMS.FMD.REC.1399.407

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.01

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Death

Timepoint

14,3,2,1,0 days after the start of the intervention

Method of measurement

The ratio of death to total patients in each group

2

Description

Recovery and discharge from the hospital

Timepoint

End of treatment

Method of measurement

Examine the patient and perform tests

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

End of study

Method of measurement

File information

2

Description

Need to be admitted to the ICU (Intensive care units)

Timepoint

After the intervention

Method of measurement

See the patient's clinical signs and tests

3

Description

Requires four drug treatments

Timepoint

During treatment

Method of measurement

Patient examination

Intervention groups

1

Description

Intervention group: out of 300 patients, 150 patients with coronary artery from two medical centers (Rasoul Akram Hospital and Firoozgar Hospital) hydroxychloroquine phosphate treatment regimen 400 mg every 12 hours on the first day and then 200 mg every 12 hours for 5 to 7 Day + Sovodak (sofosbuvir + Daklatasvir) will be taken once a day (60/400 mg) for at least 5 to 7 days. Sovodak drug manufacturer is Faravan Rojan Mohaghegh Daroo (made in Iran) and chloroquine manufacturing company is Iran Daru (made in Iran).

Category

Treatment - Drugs

2

Description

Intervention group: out of 300 patients, 150 patients with coronary artery from two medical centers (Rasoul Akram Hospital and Firoozgar Hospital) Hydroxychloroquine phosphate treatment regimen 400 mg single dose + lupinavir / ritonavir combination 400/100 twice daily They will receive at least 5 days. The manufacturer of the drug is lupinavir / ritonavir (Kaletra), Gilead (made in Iran) and the manufacturer of chloroquine, Iran Daru (made in Iran).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Mahin Jamshidi Makiani

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2

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Mahin Jamshidi Makiani

Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

Infectious diseases

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

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

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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