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)

Phone

+98 21 8893 7383

Email address

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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 Keltra 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 + lupinavir / 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 pharmacologist, 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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Firoozgar Hospital, Beh Afarin Street, Vali Asr Square
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jamshidimakiani.m@iums.ac.ir

2

Recruitment center
Name of recruitment center
Rasoul Akram Hospital
Full name of responsible person
Mahin Jamshidi Makiani

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Rasoul Akram Hospital, Niyayesh Street, Sattarkhan Street,
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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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amotevalian@iums.ac.ir
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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Person responsible for updating data

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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