Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating efficacy and safety of sofosbuvir/ ledipasvir in treatment of COVID-19

Protocol summary

Study aim
Evaluating efficacy and safety of sofosbuvir/ledipasvir in treatment of COVID-19

Design
This is an open-label, randomized clinical trial to assess efficacy and safety (phase 2-3) of sofosbuvir/ledipasvir in treatment of COVID-19. Fifty eligible patients will be assigned to intervention or control group according the permuted block randomization.

Settings and conduct
After introduction of the study protocol for patients admitted to Imam Khomeini Hospital, Tehran, Iran, and recording consent form, eligible patients will be recruited. Patients will be assigned to the intervention or the control group. Concomitant with the recommended national committee regimen, patients in the intervention group will receive sofosbuvir/ledipasvir 400/90 mg daily for 10 days. The control group will only receive the recommended national committee regimen. During the study period, patients will be monitored for response to the treatment and complications.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 18-75 years old persons with highly suspected or confirmed COVID-19 Exclusion criteria: History of drug allergy, pregnancy and lactation

Intervention groups
Included patients will assign to intervention or control group according the permuted block randomization. Concomitant with the national proposed combination, the intervention group will receive one tablet of Sofosbuvir/ledipasevir 400/90 mg daily for 10 days. Patents in the control group will receive only the national proposed combination. Patients will be followed every daily for response to the treatment and adverse reactions up to the end of treatment.

Main outcome variables
Primary endpoints of the study are rates of treatment response and adverse drug reactions. Secondary endpoints are duration of hospitalization and patients' clinical outcomes.

General information

Reason for update
Edition of the interventions due to changes in the national protocol

Acronym

IRCT registration information
IRCT registration number: **IRCT20100228003449N29**
Registration date: **2020-03-19, 1398/12/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-25, 1399/01/06**
Update count: **1**

Registration date
2020-03-19, 1398/12/29

Registrant information

Name
Hossein Khalili

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 6695 4715

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khalilih@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-18, 1398/12/28

Expected recruitment end date
2020-05-17, 1399/02/28

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating efficacy and safety of sofosbuvir/ ledipasvir in treatment of COVID-19

Public title
Effect of sofosbuvir/ ledipasvir on COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with highly suspected diagnosis of COVID-19 Patients with confirmed diagnosis of COVID-19 Patients who are candid for hospitalization Patients who are candid for starting triple-drug combination
Exclusion criteria:
History of drug allergy Pregnancy Lactation
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done according to the blocks randomization method. Regarding to the sample size, 5 patients will be include in each block. SAS procedure PROC PLAN will be applied to generate the randomization schedule. This is a non-blinded randomized clinical trial.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University Of Medical Sciences
Street address
Ghods Ave. Tehran University of Medical Sciences, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417614411
Approval date
2020-03-17, 1398/12/27
Ethics committee reference number
IR.TUMS.VCR.REC.1398.1074

Health conditions studied

1

Description of health condition studied
COVID-19 pneumonia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Response to the treatment (improvement of patients' chief complaint, abnormal paraclinic and radiologic findings)
Timepoint
Daily
Method of measurement
According the clinical, paraclinical and laboratory findings

2

Description
Gastrointestinal complications
Timepoint
Daily
Method of measurement
Interview and patient's record

3

Description
Cutaneous complications
Timepoint
Daily
Method of measurement
Interview and patient's record

4

Description
Neurological complications
Timepoint
Daily
Method of measurement
Interview and patient's record

5

Description
Renal complications
Timepoint
Daily
Method of measurement
Interview and patient's record

6

Description
Hematological complications
Timepoint
Daily
Method of measurement
Interview and patient's record

Secondary outcomes

1

Description
Duration of hospitalization
Timepoint
End of the treatment
Method of measurement
Patient's record

2

Description
Clinical outcome (cure or death)
Timepoint
End of treatment
Method of measurement
Patient's record

Intervention groups

1

Description
Intervention group: Concomitant with the national corona treatment recommendation (Tab hydroxychloroquine 400 mg twice daily at day 1 then 200 mg twice daily plus Tab lopinavir/ritonavir 200/50 mg two tablets twice daily for at least 5 days), patients will receive one tablet of sofosbuvir/ledipasvir 400/100 mg (Danesh Pharmaceutical Development Company) daily for 10 days.
Category
Treatment - Drugs

2

Description
Control group: Patients will receive the national corona treatment recommendation (Tab hydroxychloroquine 400 mg twice daily at day 1 then 200 mg twice daily plus Tab lopinavir/ritonavir 200/50 mg two tablets twice daily for at least 5 days).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Hossein Khalili
Street address
Keshavarz Boulveard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
Street address
Vice Chancellor for Research, Tehran University of Medical Sciences, Ghods Ave., Tehran, Iran
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02166706141
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msahrai@sina.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Hossein Khalili
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran
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Person responsible for scientific inquiries

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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
Results of the study will be published. The study protocol and statistical analysis will be included in the manuscript
When the data will become available and for how long
One year after finishing the study, data will be published and will be available in databases
To whom data/document is available
After permission form the sponsor, data of the study will be available for academic researchers, physicians and scientific institutes
Under which criteria data/document could be used
Other researchers are permitted to included the results

in their systematic reviews and metaanalysis

From where data/document is obtainable

For this you may ask Hossein Khalili through following information: Address: Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave.,Tehran, Iran Postal code: 1417614411 E-mail: khalilih@tums.ac.ir

What processes are involved for a request to access data/document

After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks

Comments