

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Randomized trial of additional treatments for COVID-19 in hospitalized patients who are all receiving the local standard of care- Iranian SOLIDARITY multicentre trial

Protocol summary

Study aim

Main Aim: To evaluate the safety and efficacy of medications in treating COVID-19 Specific Aims: -To evaluate the safety and efficacy of Remdesivir in treating COVID-19 -To evaluate the safety and efficacy of Chloroquine/Hydroxychloroquine in treating COVID-19 - To evaluate the safety and efficacy of Lopinavir/Ritonavir in treating COVID-19 -To evaluate the safety and efficacy of Lopinavir/Ritonavir along with Interferon in treating COVID-19 -To compare the efficacy of medications in treating COVID-19

Design

Five-Arm, Multi-center, randomized controlled trial

Settings and conduct

This trial will be performed in 30 hospitals throughout Iran. Clinicians will randomize patients using the study website and provide the appropriate treatment per protocol.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: -Adults (age ≥ 18) -Hospitalised with definite COVID-19 diagnosis, not already receiving any of the study medications -No known allergy or contraindications to any of the study medications - Patients admitted to collaborating hospitals, without anticipated transfer within 72 hours Exclusion Criteria: - Anyone having a significant contraindication to any one of the study drugs -Serious chronic liver or heart disease -Pregnancy

Intervention groups

- Local standard of care alone OR local standard of care plus one of:
 - Remdesivir (daily infusion for 10 days)
 - Chloroquine or Hydroxychloroquine (two oral loading doses, then orally twice daily for 10 days) [NB Some collaborating hospitals will study chloroquine, others hydroxychloroquine]
 - Lopinavir with Ritonavir (orally twice daily for 14 days)
 - Lopinavir with Ritonavir (ditto) plus Interferon (daily injection for 6 days).

Main outcome variables

Main Outcome: All-cause mortality Major Secondary Outcomes: -Duration of hospitalization -Time to ventilation (ICU Care)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200405046953N1**
Registration date: **2020-04-06, 1399/01/18**
Registration timing: **prospective**

Last update: **2020-04-06, 1399/01/18**

Update count: **0**

Registration date

2020-04-06, 1399/01/18

Registrant information

Name

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Name of organization / entity

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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
Randomized trial of additional treatments for COVID-19 in hospitalized patients who are all receiving the local standard of care- Iranian SOLIDARITY multicentre trial

Public title
Comparison of therapies for COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults (age ≥ 18) Hospitalised with definite COVID-19 diagnosis, not already receiving any of the study medications No known allergy or contraindications to any of the study medications Patients admitted to collaborating hospitals, without anticipated transfer within 72 hours

Exclusion criteria:

Anyone having a significant contraindication to any one of the study drugs Serious chronic liver or heart disease Pregnancy

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **3000**

Randomization (investigator's opinion)
Randomized

Randomization description
Given that this study is part of the SOLIDARITY Trial by the World Health Organization, the randomization method is only known by the Principal Investigators. Patients will be randomized through the study website equally between all the locally available treatment regimens (5 possibilities if all study drugs are locally available, fewer if not) • Local standard of care alone, OR local standard of care plus one of • Remdesivir (daily infusion for 10 days) • Chloroquine or Hydroxychloroquine (two oral loading doses, then orally twice daily for 10 days) [NB Some collaborating hospitals will study chloroquine, others hydroxychloroquine] • Lopinavir with Ritonavir (orally twice daily for 14 days) • Lopinavir with Ritonavir (ditto) plus Interferon (daily injection for 6 days).

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

National Institute for Medical Research Development (NIMAD)

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Approval date

2020-04-02, 1399/01/14

Ethics committee reference number

IR.NREC.1399.001

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Primary Outcome: All-cause mortality

Timepoint

Any time death or discharge of patients occurs

Method of measurement

Death certificate signed by hospital clinicians or discharge documents

Secondary outcomes

1

Description

Duration of Hospital Stay

Timepoint

Any time during the study

Method of measurement

Based on Medical Charts

2

Description

Time to ventilation (ICU Care)

Timepoint

Any time during the study

Method of measurement

Based on Medical Chart

Intervention groups

1

Description

Intervention group: local standard of care plus Remdesivir (daily infusion for 10 days)

Category

Treatment - Drugs

2

Description

Intervention group: local standard of care plus Chloroquine or Hydroxychloroquine (two oral loading doses, then orally twice daily for 10 days)

Category

Treatment - Drugs

3

Description

Intervention group: local standard of care plus Lopinavir with Ritonavir (orally twice daily for 14 days)

Category

Treatment - Drugs

4

Description

Intervention group: local standard of care plus Lopinavir with Ritonavir (ditto) plus Interferon (daily injection for 6 days).

Category

Treatment - Drugs

5

Description

Control group: local standard of care

Category

Treatment - Drugs

Recruitment centers

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian Ministry of Health and Medical Education,
Deputy of Research and Technology

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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

Iranian Ministry of Health and Medical Education, Deputy
of Research and Technology

Proportion provided by this source

50

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
Other

Person responsible for general inquiries

Contact

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Tehran University of Medical Sciences
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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

Data collected in this study belongs to the World Health Organization SOLIDARITY Trial.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The study protocol and the informed consent use will be shared after the completion of the study, if requested.

When the data will become available and for how long

Not Applicable

To whom data/document is available

The documents will be made available to any interested researcher, affiliated with a university/institution wanting to use them.

Under which criteria data/document could be used

There are no specific criteria for use.

From where data/document is obtainable

Documents can be obtained from the central committee of the SOLIDARITY Trial in Iran--Dr. Hossein Poustchi or Dr. Minoos Mohraz.

What processes are involved for a request to access

data/document

Formal request from the researcher interested, in their affiliated university's letterhead sent to Dr. Hossein

Poustchi.

Comments