Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Randomzied 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 Lopinovir/Retinovir in treating COVID-19 -To evaluate the safety and efficacy of Lopinovir/Retinovir 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

Hossein Poustchi

Name of organization / entity

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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

Randomzied 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 heat 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
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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

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hossein Poustchi

Position

Associate Professor

Latest degree

Ph.D.

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

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. Minoo 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