

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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 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  $\geq 18$ ) -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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8241 5204

##### Email address

h.poustchi@gmail.com

##### 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  $\geq 18$ ) 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)

**Street address**

No. 21, Be'sat Alley, East Fatemi St. Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1419693111

**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**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Baharloo Hospital

##### **Full name of responsible person**

Hadiseh Hosami

##### **Street address**

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### 2

#### **Recruitment center**

##### **Name of recruitment center**

Imam Khomeini Hospital Complex

##### **Full name of responsible person**

Mohammad Reza Salehi

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### 3

#### **Recruitment center**

##### **Name of recruitment center**

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##### **Full name of responsible person**

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### 4

#### **Recruitment center**

##### **Name of recruitment center**

Flroozgar Hospital

##### **Full name of responsible person**

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**Recruitment center**

**Name of recruitment center**

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**Recruitment center**

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**Recruitment center**

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### Recruitment center

**Name of recruitment center**

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### Recruitment center

**Name of recruitment center**

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### Recruitment center

**Name of recruitment center**

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### Recruitment center

**Name of recruitment center**

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### Recruitment center

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### Recruitment center

**Name of recruitment center**

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**Full name of responsible person**

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### Recruitment center

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### Recruitment center

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### Recruitment center

**Name of recruitment center**

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### Recruitment center

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Ayatollah Khansari Hospital

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### **Recruitment center**

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### **Recruitment center**

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### **Recruitment center**

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### **Recruitment center**

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### **Province**

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## 30

### **Recruitment center**

**Name of recruitment center**

Boo Ali Sina Hospital

**Full name of responsible person**

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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

**Full name of responsible person**

Reza Malekzadeh

**Street address**

Shahrake Gharb, Falamak St.

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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**  
Epidemiology  
**Street address**  
Karegare Shomali St. Shariati Hospital  
**City**  
Tehran  
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1411713135  
**Phone**  
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h.poustchi@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Minoos Mohraz  
**Position**  
Professor  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Infectious diseases  
**Street address**  
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**City**  
Tehran  
**Province**  
Tehran  
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**Email**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Hossein Poustchi  
**Position**  
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**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Epidemiology  
**Street address**  
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**Province**  
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**Postal code**  
1411713135  
**Phone**  
+98 21 8241 5204  
**Email**  
h.poustchi@gmail.com

## 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**