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/Ritonovir in treating COVID-19 -To evaluate the safety and efficacy of Lopinovir/Ritonovir 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) -Hospitalized 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
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)
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 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**

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**Randomization (investigator’s opinion)**

Randomized

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**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

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Approval date

- 2020-04-02, 1399/01/14

Ethics committee reference
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
Time to ventilation (ICU Care)

Any time during the study

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).

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**Recruitment centers**

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<td>Ilad Alavi Darazam</td>
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Recruitment center

**Name of recruitment center**
Masih Danesvari Hospital

**Full name of responsible person**
Payam Tabarsi

**Street address**
Shahid Bahonar St. Darabad St.

**City**
Tehran

**Province**
Tehran

**Postal code**
1956944413

**Email**
payamtabarsi@yahoo.com
### Recruitment center

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<td>Email</td>
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IRCT | Randomized trial of additional treatments for COVID-19 in hospitalized patients who are all receiving the local standard of care- Iranian SOLIDARITY trial

Shariati Hospital

**Full name of responsible person**
Saeid Hafizi Lotfabadi

**Street address**
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**Province**
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---

**Recruitment center**

Name of recruitment center
Ali Asghar Hospital

**Full name of responsible person**
Mohsen Moghadami

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**City**
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**Province**
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**Postal code**
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---

**Recruitment center**

Name of recruitment center
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11

Recruitment center

Name of recruitment center
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12

Recruitment center

Name of recruitment center
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13

Recruitment center

Name of recruitment center
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14

Recruitment center

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Recruitment center

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City
Isfahan

Province
Isfahan

Postal code
8174675731

Email
Farzin300@gmail.com

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**17**
Esabne Maryam Hospital

**Full name of responsible person**
Mehrdad Salahi

**Street address**
Shams Abadi St.

**City**
Isfahan

**Province**
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**Postal code**
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---

19

**Recruitment center**

Razi Hospital

**Full name of responsible person**
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**Email**
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---

20

**Recruitment center**

**Name of recruitment center**
Razi Hospital

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Recruitment center

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City
Sari

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Mazandaran

Postal code
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Email
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Recruitment center

Name of recruitment center
Valiasr Hospital

Full name of responsible person
Behnam Mahmoodieh

Street address
Hazrate Valiasr Sq.

City
Arak

Province
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Postal code
3814957558

Email
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Recruitment center

Ayatollah Rohani Hospital

Full name of responsible person
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Postal code
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Email
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28

Recruitment center

Name of recruitment center
Yahyanejad Hospital

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Madaras St. Mostafa Khomeini St.

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Province
Mazandaran

Postal code
1111111111

Email
mjavanian@gmail.com
Modarres Hospital

**Full name of responsible person**
Hassan Mozaffar

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Motahari St. Modares Blvd.

**City**
Saveh

**Province**
Markazi

**Postal code**
1111111111

**Email**
Hassan.mozaffar@gmail.com

---

Recruitment center

Shahid Chamran Hospital

**Full name of responsible person**
Mehdi Mesri

**Street address**
Tehran Old Route, Golha Route

**City**
Saveh

**Province**
Markazi

**Postal code**
1111111111

**Email**
Mesrimd@gmail.com

---

Recruitment center
Boo Ali Sina Hospital

Full name of responsible person
HamidReza Najjari

Street address
BooAli St.

City
Qazvin

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Qazvin

Postal code
1111111111

Email
Mrpthndr1382@yahoo.com

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.

City
Tehran

Province
Tehran

Postal code
1111111111

Phone
+98 21 8241 5000

Email
dr.reza.malekzadeh@gmail.com
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**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
Person responsible for scientific inquiries

Contact

**Name of organization / entity**
Tehran University of Medical Sciences

**Full name of responsible person**
Minoo Mohraz

**Position**
Professor

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Infectious diseases

**Street address**
Keshavarz Blvd. Gharib St.

**City**
Tehran

**Province**
Tehran

**Postal code**
1419733141
### Person responsible for updating data

**Contact**

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<td>Hossein Poustchi</td>
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<td>Email</td>
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### Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

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</tbody>
</table>
Documents can be obtained from the central committee of the SOLIDARITY Trial in Iran—Dr. Hossein Poustchi or Dr. Minoo Mohraz.

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

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