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

More options

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

1

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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Full name of responsible person
Hossein Poustchi

Position
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Latest degree
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Other areas of specialty/work
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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)

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	

Tel:
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8:00 - 15:30 Tehran time
11:30 - 19:00 GMT

0098 21 8670 5503

During COVID-19 Epidemic at working times:
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Email:
admin@irct.ir (mailto:admin@irct.ir)

Directly contacting the manager:
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