# SOLIDARITY TRIAL PLUS: An international randomized trial of additional treatments for COVID-19 in hospitalized patients who are all receiving the local standard of care

Submission date	Recruitment status	[X] Prospectively registered
20/04/2021	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
29/07/2021	Completed	Results
Last Edited	Condition category Infections and Infestations	Individual participant data
09/10/2024		[X] Record updated in last year

#### **Plain English Summary**

Background and study aims

COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

The World Health Organization (WHO) helps evaluate drugs by randomizing their effects on important outcomes. The WHO Solidarity trial involves collaboration between hundreds of hospitals in dozens of countries. It began by evaluating four repurposed drugs and now guided by an independent Expert Group, is now evaluating addition to the local Standard of Care of other potential drugs.

#### Who can participate?

Adults (age 18 years or older), hospitalized with laboratory-confirmed COVID at one of the participating hospitals

#### What does the study involve?

Once electronic data collection has been completed the patient automatically enters the trial and a random allocation of their trial treatment is generated (by an algorithm that ensures eventual balance in the characteristics just recorded between each study drug and its controls) and displayed. The patients will be randomly allocated either to Standard of Care (SoC) or to one of the study drugs.

What are the possible benefits and risks of participating?

At all times the patient's medical team remains solely responsible for decisions about that patient's care and safety. Hence, if the team decides that deviation from the randomly allocated

treatment is appropriate for a particular patient, this should be done, regardless of the random allocation. That patient would still be part of the trial, regardless of what treatment they were actually given.

Where is the study run from?
The World Health Organization (Switzerland)

When is the study starting and how long is it expected to run for? June 2021 to November 2023

Who is funding the study?
The World Health Organization (Switzerland)

Who is the main contact?

Dr Ana Maria Henao Restrepo, henaorestrepoa@who.int

Dr Marie-Pierre Preziosi, preziosim@who.int

## Study website

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments

# Contact information

# Type(s)

Scientific

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# Additional identifiers

EudraCT/CTIS number 2020-001784-88

**IRAS** number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers 1.0

# Study information

#### Scientific Title

An international randomized trial of additional treatments for COVID-19 in hospitalized patients who are all receiving the local standard of care

#### Acronym

**SOLIDARITY Plus** 

# Study hypothesis

The primary analysis will assess any effects of treatment allocation on all-cause in-hospital mortality in all patients. The main secondary analyses will assess in-hospital mortality subdivided by initial respiratory support. Further secondary analyses will assess the initiation of ventilation in lower-risk patients, and, separately, the duration of hospital stay in lower-risk patients and in higher-risk patients.

# Ethics approval required

Ethics approval required

# Ethics approval(s)

Approved 23/06/2021, COVID-19 Research Ethics Review Committee (WHO COVID-19 ERC) (20 Avenue Appia, Geneva, 1211, Switzerland; +41 227912174; ersec@who.int), ref: CERC.0114

# Study design

Interventional randomized controlled trial

# Primary study design

#### Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

# Study type(s)

Treatment

#### Participant information sheet

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments

#### Condition

Additional treatments for COVID-19 in hospitalized patients who are all receiving the local standard of care

#### **Interventions**

Once electronic data collection has been completed the patient automatically enters the trial and a random allocation of their trial treatment is generated (by an algorithm that ensures eventual balance in the characteristics just recorded between each study drug and its controls) and displayed. The patients will be randomly allocated either to Standard of Care (SoC) alone or to one of the study drugs + SoC.

- 1. Artesunate: 2.4 mg/kg/dose at 0 hours, 12 hours, and 24 hours and thereafter every 24 hours; IV injection; duration of treatment 7 days. This is the standard dose recommended for the treatment of severe malaria
- 2. Infliximab: 5 mg/kg/dose (once only), single IV infusion over 2 hours. This is the standard dose that is given repeatedly for the treatment of psoriasis
- 3. Imatinib: 400 mg/dose; orally once daily; duration of treatment 14 days. This is the standard maintenance dose which is at the lower end of that used for several years in the treatment of hematological malignancies

Follow-up: All randomised participants are to be followed up until death or discharge from hospital.

# Intervention Type

Drug

#### Phase

Not Applicable

# Drug/device/biological/vaccine name(s)

Artesunate, infliximab, imatinib

#### Primary outcome measure

In-hospital mortality in all patients measured using patient records up to the end of hospital stay

# Secondary outcome measures

Measured using patient records:

- 1. Initial respiratory support (yes/no)
- 2. Initiation of ventilation in lower-risk patients (yes/no)
- 3. Duration of hospital stay (days)

# Overall study start date

23/06/2021

#### Overall study end date

14/11/2023

# **Eligibility**

#### Participant inclusion criteria

The only patients invited will be those admitted to a collaborating hospital; no wider recruitment is expected.

- 1. Adults (age ≥18 years, which allows consent)
- 2. Recently hospitalized (or already in hospital) with laboratory-confirmed COVID
- 3. Not expected to be transferred within 72 hours
- 4. With, in the view of their doctors, no contra-indication to any potentially relevant study drug

#### Participant type(s)

**Patient** 

#### Age group

Adult

# Lower age limit

18 Years

#### Sex

Both

# Target number of participants

No specific sample size is specified in this public health emergency core protocol. Interim results will be kept under review by an independent Global Data and Safety Monitoring Committee, and this Committee will decide how often to conduct interim analyses. It is anticipated that at least several thousand patients will need to be recruited into the trial to give reliable answers.

# Participant exclusion criteria

Does not meet inclusion criteria

#### Recruitment start date

02/08/2021

#### Recruitment end date

31/03/2023

# Locations

Colombia
Dominican Republic
Egypt
Ethiopia
Finland
Honduras
India
Ireland
Kenya
Latvia
Lebanon
Lithuania
Malaysia
Mali
Mozambique
Nepal
Nigeria
North Macedonia
Pakistan
Panama

Countries of recruitment

Albania

Argentina

Bangladesh

Botswana

Brazil

Canada

Paraguay

Philippines

Portugal

Switzerland

Tunisia

Zimbabwe

Study participating centre
Multiple hospital sites (to be confirmed)
Multiple hospital sites (to be confirmed)
Globally, many cities
Switzerland
1211

# Sponsor information

# Organisation

World Health Organization

# Sponsor details

Avenue Appia 20 Geneva Switzerland 1211 +41 22 791 3402 salamik@who.int

# Sponsor type

Research organisation

#### Website

https://www.who.int

#### **ROR**

https://ror.org/01f80g185

# Funder(s)

# Funder type

#### Research organisation

#### **Funder Name**

World Health Organization

#### Alternative Name(s)

, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , BO3, OMS

## Funding Body Type

Private sector organisation

#### **Funding Body Subtype**

International organizations

#### Location

Switzerland

# **Results and Publications**

# Publication and dissemination plan

This international collaboration is co-ordinated through the World Health Organisation, which is also a sponsor of the trial. Any wholly reliable interim findings will be disseminated rapidly by the WHO. There will be group authorship recognizing the contribution of all national and local investigators and guided by the International Committee of Medical Journal Editors (ICMJE) recommendations. Although the writing committee will consist of the executive group and the WHO trial secretariat, authorship will include all steering committee members and local collaborators whose hospital, in the view of the national PI, contributed substantially towards the trial.

## Intention to publish date

31/03/2025

# Individual participant data (IPD) sharing plan

After the trial has ended and its results have been reported, anonymized data sharing will occur as per the Policy Statement on Data Sharing by the World Health Organization (https://www.who.int/ihr/procedures/SPG\_data\_sharing.pdf?ua=1&ua=1)

# IPD sharing plan summary

Available on request