

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 20/04/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/07/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/10/2024	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

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?

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Contact information

Type(s)

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Additional identifiers

Clinical Trials Information System (CTIS)
2020-001784-88

Protocol serial number
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 objectives

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

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(s)

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

Key secondary outcome(s)

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)

Completion date

14/11/2023

Eligibility

Key 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

02/08/2021

Date of final enrolment

31/03/2023

Locations**Countries of recruitment**

Albania

Argentina

Bangladesh

Botswana

Brazil

Canada

Colombia

Dominican Republic

Egypt

Ethiopia

Finland

Honduras

India
Ireland
Kenya
Latvia
Lebanon
Lithuania
Malaysia
Mali
Mozambique
Nepal
Nigeria
North Macedonia
Pakistan
Panama
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

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, , ВОЗ, OMS

Funding Body Type

Government organisation

Funding Body Subtype

International organizations

Location

Switzerland

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes