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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

Registration date
29/07/2021

Overall study status
Completed

Last Edited
09/10/2024

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[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
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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

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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

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

Sponsor details
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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, , ВОЗ, 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