ISRCTN15779782 https://doi.org/10.1186/ISRCTN15779782

Solidarity trial of candidate vaccines against COVID-19

Submission date
03/08/2021

Recruitment status
No longer recruiting

Registration date
08/10/2021

Overall study status
Completed

Last Edited
25/07/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This large, international, randomized controlled clinical trial is designed to enable an expeditious, agile, and concurrent evaluation of the benefits and risks of multiple candidate preventive vaccines against COVID-19 at international sites with sufficient COVID-19 attack rates. The trial is designed to provide sufficient evidence of safety and vaccine efficacy against COVID-19 to support decision-making about global vaccine deployment, which may include licensure and/or WHO pre-qualification. Final decisions about COVID-19 deployment will be made in each jurisdiction.
Simplicity of procedures: Within each country, the investigator invites selected sites and helps them get ethical and regulatory approval and study vaccines, then volunteers' recruitment can begin. To facilitate collaboration, volunteer enrolment and randomisation (via a cloud-based GCP-compliant platform) and all other trial procedures are greatly simplified, and no paperwork is required. Once consent has been obtained, electronic entry of anonymised details of a few key characteristics of each volunteer takes only a few minutes. At the end of a patient's entry, a random vaccine allocation is generated.

Who can participate?
Adults (age ≥ 16 years), capable of giving personal signed informed consent, healthy participants who are determined by the clinical judgment of the investigator to be eligible for inclusion in the study.

What does the study involve?
Trial entry, randomization: Once electronic data collection has been completed the volunteer automatically enters the trial and a random allocation of their trial vaccine is generated (by an algorithm that ensures eventual balance in the characteristics just recorded between each study vaccines and its placebos) and displayed. The volunteers will be randomly allocated either to placebo or to one of the study vaccines.
Follow-up: Each participant will be contacted weekly for 52 weeks for information as to whether any potentially relevant symptoms have arisen, with laboratory testing triggered if the report suggests COVID-19.

What are the possible benefits and risks of participating?
Safety: Evaluation of COVID-19 vaccine safety is one of the primary objectives of this trial. All sites will monitor and report serious adverse events (SAEs) at any time after vaccination, by baseline SARS-CoV-2 serostatus where available.

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

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

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

Who is the main contact?
Dr Ana Maria Henao Restrepo, henaorestrepoa@who.int

Study website
https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-trial-of-covid-19-vaccines

Contact information

Type(s)
Scientific

Contact name
Dr Ana Maria Henao Restrepo

ORCID ID
http://orcid.org/0000-0001-9910-7999

Contact details
Medical Officer
HQ/RDB R&D Blue Print
(HQ/HEO/RDB)
World Health Organization HQ
Geneva
Switzerland
1211
+41 795130039
henaorestrepoa@who.int

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
An international randomised trial of candidate vaccines against COVID-19

Acronym
SOLIDARITY Vaccine Trial

Study objectives
This large, international, randomized controlled clinical trial is designed to enable an expeditious, agile, and concurrent evaluation of the benefits and risks of multiple preventive vaccines against COVID-19 at international sites with sufficient COVID-19 attack rates. The trial is designed to provide sufficient evidence of safety and vaccine efficacy against COVID-19 to support decision-making about global vaccine deployment, which may include licensure and/or WHO pre-qualification. Final decisions about COVID-19 deployment will be made in each jurisdiction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/06/2022, WHO Ad Hoc COVID-19 Research Ethics Review Committee (World Health Organization, 20, Avenue Appia, Geneva 1211, Switzerland; +41 (0)22 791 2174; ersec@who.int, mumforde@who.int), ref: not applicable

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
Four vaccine candidates selected for evaluation. Candidate vaccines are selected on a rolling basis by the WHO Working Group on vaccine prioritization

Trial entry, randomization: Once electronic data collection has been completed the volunteer automatically enters the trial and a random allocation of their trial vaccine is generated (by an algorithm that ensures eventual balance in the characteristics just recorded between each study vaccines and its placebos) and displayed. The volunteers will be randomly allocated either to placebo or to one of the study vaccines.

Follow-up: Each participant will be contacted weekly for 52 weeks for information as to whether any potentially relevant symptoms have arisen, with laboratory testing triggered if the report suggests COVID-19.

Adaptive design: A global Data Monitoring Committee will keep the accumulating safety results and major outcome results under regular review. Different candidate vaccines may be available or suitable to enter the trial at different times; for each candidate vaccine, the primary efficacy results are expected within 3-6 months of the vaccine entering the trial. By using a shared placebo/control group and a common Core protocol to evaluate multiple candidate vaccines in the trial, resources allocated to the evaluation of each candidate vaccine are judiciously saved while a high standard of scientific rigor and efficiency is ensured.

Add-on studies: Particular countries, or particular groups of sites, may want to collaborate in making further measurements or observations. These could be thought of as Phase 2b trials that are being conducted concurrently with the Phase 3 trial. However, while well-organised additional research studies of additional secondary and supportive endpoints, for which monitoring is valuable but optional at each study site include infection with SARS-CoV-2, transmission of SARS-CoV-2, and possible immunological markers as correlates of risk could well be valuable, they are not core requirements in every site.

Intervention Type
Biological/Vaccine

Phase
Phase III

Drug/device/biological/vaccine name(s)
Candidate Vaccines

Primary outcome measure
Virologically confirmed COVID-19 disease, through SARS-CoV2 RNA isolation and RRT-PCR amplification in oro-nasopharyngeal specimen, regardless of disease severity, at 14, 180, 365 days after the last dose.

Secondary outcome measures
Measured at dose 1, dose 2, 7, 180, and 365 days after dose 2:
1. Serious adverse events (SAEs), adverse events of special interest (AESIs) as requested, collected for all participants throughout the study.

2. Severe COVID-19 (as per WHO classification) and death with recently confirmed COVID-19.
3. COVID-19 and severe COVID-19 diagnosed starting 14 days after the final dose through the final study visit.
4. SARS-CoV-2-specific neutralization antibody, binding antibody, and T-cell immune responses measured using blood test in a subset of participants at selected sites.
5. COVID-19 viral load and other disease progression biomarkers measured using blood test.

Overall study start date
03/08/2021

Completion date
30/10/2024

Eligibility

Key inclusion criteria
1. Male or female participants between the ages of 16 and above at randomization
2. Living in the area and planning to reside in the area for at least 6 months
3. Capable of giving personal signed informed consent/have parent(s)/legal guardian capable of giving signed informed consent as described in SOP-03
4. Healthy participants who are determined by the clinical judgment of the investigator to be eligible for inclusion in the study
5. Participants who are willing and able to comply with all scheduled visits, vaccination plans, laboratory tests (if randomised and consent given, lifestyle considerations, and other study procedures

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit
16 Years

Sex
Both

Target number of participants
The trial is endpoint driven, as the main analysis for each vaccine arm versus the concurrent shared placebo/control arm is triggered by occurrence of a total of 150 cases of COVID-19 across these two arms, at which point the results will be reported but blinded follow-up will continue. This fixed num-ber of 150 endpoints is set to provide sufficient power to detect a predefined target level of VE, reject-ing the initially specified null hypothesis that VE is < 30%. For example, for the 150-endpoint design noted above, where a 50:100 vaccine:placebo endpoint split just meets success criteria, if the 6-month COVID-19 attack rate in the placebo arm is 1-2%, and par-ticipants are enrolled evenly over 3 months, then a total evaluable sample size of about 20,000 per vaccine arm, with an equal number in the shared-placebo arm is expected to yield the needed end-points within 2 to 4 months after the median enrolment date.

Key exclusion criteria
1. Previous laboratory-confirmed diagnosis of COVID 19.
2. Previous vaccination with any COVID-19 vaccine.
3. Receipt of medications intended to prevent COVID 19.
4. Participation in other studies involving a study intervention within 28 days prior to study entry and/or during study participation.
5. History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s).
6. Individuals who receive treatment with immunosuppressive therapy, including cytotoxic agents or systemic corticosteroids, eg, for cancer or an autoimmune disease, or planned receipt throughout the study.
7. Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection.
8. Women who are pregnant or breastfeeding will be informed that there is no data on the safety of these vaccines among these groups and will be given the opportunity to decide if they are willing to participate in the trial.

Date of first enrolment
01/09/2021

Date of final enrolment
01/08/2023

Locations

Countries of recruitment
Colombia

Kenya

Mali

Philippines

Sierra Leone

Switzerland

Study participating centre
Multicountry trial
Geneva
Switzerland
1211

Sponsor information

Organisation
World Health Organization

Sponsor details
Avenue Appia 20
Geneva
Switzerland
1211
+41 22712111
salamik@who.int

Sponsor type
Government

Website
http://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 coordinated 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. Alt-hough 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 principal investigator, contributed substantially towards the trial.

Intention to publish date
31/01/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. 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
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	14/06/2021	16/09/2021	No	No
Protocol file	version 4.1	20/05/2022	12/09/2022	No	No