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SOLIDARITY PARTNERS trial

Submission date
03/10/2024

Recruitment status
No longer recruiting

Registration date
04/10/2024

Overall study status
Completed

Last Edited
17/11/2025

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 of protocol

Background and study aims
Some filoviruses are dangerous to humans and can make people very sick or cause them to die. Two diseases caused by them – Ebola and Marburg – have caused outbreaks in countries in Africa. When these outbreaks happen they can cause lots of damage in communities, and cause problems for the country like children being out of school and businesses closing. It is hard to know exactly when and where outbreaks will happen next. This makes it hard to develop treatments to fight them. The best way to find out if a drug works and is safe is to run a clinical trial. People agree to take part and some are given the vaccine or treatment. What they receive is decided at random (like tossing a coin) to ensure that the results are reliable. All participants are followed up to check for side effects and to find out what happens to them. The World Health Organization is organizing this clinical trial for filoviruses. It is called the SOLIDARITY PARTNERS trial and is focused on finding the best treatments for filoviruses.

Who can participate?
Patients of any age who have been admitted to a hospital or treatment unit for treatment of Ebola disease, Marburg disease, and unspecified and emergent filovirus diseases.

What does the study involve?
Participants in the study will have information collected about how they are feeling, what medications they are taking, and the results of any blood test (including Ebola or Marburg tests, malaria tests, liver and kidney tests, and if they are women - pregnancy tests that their doctors have ordered. A computer will then allocate participants at random (like rolling a die) to one (or sometimes more) of the study medicines. Neither the participant nor their doctors can choose which of these treatments will be allocated. Participants will then be given the study medicines. Participants will have some extra blood tests taken. These will be on the day they arrive, on days 3, 5, 7, 10, 13 and 16 of their stay (if they are still in the treatment unit) and on the day of discharge. Participants will then be followed up around day 28 and day 60 after entering the study. Pregnant women will be followed up to collect information on their and their baby's health.

What are the possible benefits and risks of being in the study?
It is unknown if any of the treatments being tested will have additional benefits, so the study

treatment may or may not help participants personally, but this study should help future patients. The study drugs may have side effects. The study team will monitor for side effects. Taking blood samples may cause soreness, bleeding or bruising where the needle went in.

Where is the study run from?
The study is being run by doctors from the World Health Organization and the Ministry of Health in countries affected by filovirus outbreaks.

When is the study starting and how long is it expected to run for?
February 2023 to December 2024

Who is funding the study?
The World Health Organisation.

Who is the main contact?
Prof Peter Horby, peter.horby@ndm.ox.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Pan_filo_5.0

Study information

Scientific Title
Platform Adaptive Randomised Trial for NEw and Repurposed Filovirus treatmentS (PARTNERS)

Acronym
SOLIDARITY PARTNERS

Study objectives
To identify the effect of included therapies on all-cause mortality at 28 days after randomisation in patients admitted to a healthcare facility with filovirus disease.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 30/09/2024, National Ethics Committee of the Republic of Rwanda (Ministry of Health, P.O. Box 83, Kigali, NA, Rwanda; +250 2 55 10 78 84; info@rnecrwanda.org), ref: 117 /RNEC/2024

2. approved 01/12/2023, World Helth Organization Ethics Review Committee (20 Avenue Appia, Geneva, CH-1211, Switzerland; +41-22-7912111; henaorestrepoa@who.int), ref: CERC.0196

Study design
Multi-country multi-outbreak randomized adaptive platform trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Filovirus disease: including Ebola disease, Marburg disease, and unspecified and emergent filovirus diseases.

Interventions
This is a multi-country, multi-outbreak randomised adaptive platform trial of potential treatments for filovirus disease. This includes Ebola disease, Marburg disease, and unspecified and emergent filovirus diseases.

The treatment comparisons included are determined by expert consultations convened by WHO. There are three treatment domains:
1. Monoclonal antibody
2. Small molecule antiviral
3. Host directed therapies
The specific drug in each domain varies according to the particular filovirus. As a platform adaptive trial, the included agents may vary throughout the trial as new agents or new data become available.

Randomisation is at 1:1 allocation between the ‘supportive care plus a candidate therapeutic’ and ‘supportive care with no additional treatment’ groups. A fully factorial design is used for each domain, so more than one independent randomisation can be undertaken simultaneously for a participant (one randomisation per domain, depending on the availability of candidate therapeutics in each domain).

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Initial agents are remdesivir (small molecule antiviral) and MBP091 (monoclonal antibody specific for Marburg virus disease).

Primary outcome(s)
All-cause mortality measured using patient medical records at 28 days following randomisation

Key secondary outcome(s))
Time (days) to Filovirus RNA <LLOQ (lower limit of quantitation) measured using real time reverse transcription-polymerase chain reaction within 28 days following randomisation

Completion date
29/12/2024

Eligibility

Key inclusion criteria
1. Admitted to a hospital or treatment unit for treatment of filovirus disease
2. Positive Filovirus RT-PCR (or neonate aged 7 days or younger born to a woman with acute laboratory-confirmed Filovirus Disease)
3. No medical history that might, in the opinion of the attending clinician, put the patient at significant risk if enrolled in the trial (e.g. known allergy to a study drug)
4. Not known to have been enrolled in this protocol previously

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Lower age limit
0 days

Upper age limit
110 years

Sex
All

Total final enrolment
5

Key exclusion criteria
Not meeting the participant inclusion criteria

Date of first enrolment
15/10/2024

Date of final enrolment
29/12/2024

Locations

Countries of recruitment
Rwanda

Study participating centre
Central University Teaching Hopsital
Avenue 4
Kigali
Rwanda
KK 17

Sponsor information

Organisation
World Health Organization

ROR
https://ror.org/01f80g185

Organisation
Ministry of Health

ROR
https://ror.org/05prysf28

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
Government organisation

Funding Body Subtype
International organizations

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the study will be available on request from Prof Peter Horby, peter.horby@ndm.ox.ac.uk

IPD sharing plan summary
Available on request