

SOLIDARITY PARTNERS trial

Submission date 03/10/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/10/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/10/2024	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 2030

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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 Health Organization Ethics Review Committee (20 Avenue Appia, Geneva, CH-1211, Switzerland; +41-22-7912111; henaorestrepa@who.int), ref: CERC.0196

Study design

Multi-country multi-outbreak randomized adaptive platform trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital, Laboratory, Medical and other records

Study type(s)

Treatment

Participant information sheet

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

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

Pharmaceutical study type(s)

Not Applicable

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 measure

All-cause mortality measured using patient medical records at 28 days following randomisation

Secondary outcome measures

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

Overall study start date

02/02/2023

Completion date

01/03/2031

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 seven 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

Age group

All

Lower age limit

0 Days

Upper age limit

110 Years

Sex

Both

Target number of participants

500; Ideally, each comparison should be sufficiently large to provide good power (e.g. 90% power to achieve $2P=0.01$) to detect a proportional reduction in mortality of at least one third. This may require randomisation of several hundred patients in each comparison. For example, if mortality in the reference arm was 50%^{12,18,19}, randomisation of around 520 participants in a single comparison would give more than 90% power at $2P=0.01$ to detect a proportional reduction in mortality of one-third and more than 80% power at $2P=0.05$ to detect a smaller (but still useful) reduction in mortality of one-quarter.

Key exclusion criteria

Not meeting the participant inclusion criteria

Date of first enrolment

15/10/2024

Date of final enrolment

31/12/2030

Locations

Countries of recruitment

Rwanda

Study participating centre

Central University Teaching Hospital

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Kigali

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Sponsor information

Organisation

World Health Organization

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Sponsor type

Research organisation

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Sponsor type

Government

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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

Planned publication in a peer-reviewed journal

Intention to publish date

31/12/2031

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