ISRCTN30355388 https://doi.org/10.1186/ISRCTN30355388

SOLIDARITY PARTNERS trial

Submission date 03/10/2024	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/10/2024	**Overall study status** Ongoing	
Last Edited 04/10/2024	**Condition category** Infections and Infestations	

Plain English Summary

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

Contact name
Dr Amanda Rojek

ORCID ID
http://orcid.org/0000-0002-3948-0756

Contact details
Pandemic Sciences Institute, Nuffield Department of Medicine, University of Oxford,
Old Road Campus, Roosevelt Drive.
Oxford
United Kingdom
OX3 7BN
+44 1865 270000
amanda.rojek@ndm.ox.ac.uk

Type(s)
Public

Contact name
Dr Ana Maria Henao-Restrepo

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

Contact details
World Health Organisation, 20 Avenue Appia.
Geneva
Switzerland
CH-1211

+41 22 791 21 11
henaorestrepoa@who.int

Type(s)
Principal Investigator

Contact name
Dr David Turatsinze

Contact details
CHUK MOH, KK Avenue 04
Kigali
Rwanda
KK 17
+250788317487
dturatsinzeh2001@yahoo.fr

Type(s)
Scientific

Contact name
Prof Peter Horby

ORCID ID
http://orcid.org/0000-0002-9822-1586

Contact details
Pandemic Sciences Institute, Nuffield Department of Medicine, University of Oxford,
Old Road Campus, Roosevelt Drive.
Oxford
United Kingdom
OX3 7BN
+447785604877
peter.horby@ndm.ox.ac.uk

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 hypothesis
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

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

Condition
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

Overall study end date
01/03/2031

Eligibility

Participant 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.

Participant exclusion criteria
Not meeting the participant inclusion criteria

Recruitment start date
14/10/2024

Recruitment end date
31/12/2030

Locations

Countries of recruitment
Rwanda

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

Sponsor information

Organisation
World Health Organization

Sponsor details
20 Avenue Appia
Geneva
Switzerland
CH-1211
+41 22 791 21 11
henaorestrepoa@who.int

Sponsor type
Research organisation

Website
https://www.who.int/about/contact-us

ROR
https://ror.org/01f80g185

Organisation
Ministry of Health

Sponsor details
P.O. Box 84
Kigali
Rwanda
NA
+250 577458
info@moh.gov.rw

Sponsor type
Government

Website
http://www.moh.gov.rw/

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, , 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