

THE FILO VIRUS DISEASE THERAPEUTIC TRIAL *(INCLUSION AND EXCLUSION CRITERIA)*

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Introduction

- Filo-viridae viruses can cause severe diseases with a high mortality rate. *Eg. Ebola and Marburg disease*
- Their outbreaks is devastating to the communities and the countries at large.
- The emergence of this filo-viruses , as well as where it would occur next is unpredictable. *This has made advancement of evidence-based treatment for it slow.*
- Therefore, it is important to identify suitable participant to take part in this study. So that, the effect of a range of interventions on all-cause mortality at 28 days in patients admitted to a healthcare facility with filo-virus disease would be identified.

Eligibility

- Patients are eligible for the study if all of the following are true:
 - i. Admitted to a hospital or treatment unit for treatment of filo-virus disease.
 - ii. Positive filo-virus RT-PCR (or neonate aged seven days or younger born to a woman with acute laboratory confirmed Filo virus Disease).
 - iii. 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).
 - iv. Not known to have been enrolled in this protocol previously.

OTHER ELIGIBILITY CRITERIA

- In addition, if the attending clinician believes that a patient should definitely not receive one of the active drug treatments (see virus specific annexes for contraindications), or that the patient should definitely be receiving one of the active treatments (eg.corticosteroids for a licensed indication), or they have already received a treatment in that class during their course of illness, *then they will not be eligible for randomization in that comparison.*
- **Co-enrolment in other studies and trials is not an exclusion criterion** (unless there is a risk to the validity of either trial, or if co-enrolment increases risk to participants).

Pregnancy

- There is a high maternal mortality in pregnant women with Ebola Disease, and foetal survival is rare.
- There are only three known cases of Marburg Disease in pregnant women.
- All women died, and the only neonate delivered died shortly after birth.
- **Therefore, pregnant women will be eligible for enrolment in the trial.**
- Expert obstetric and teratology advice will be provided to the Trial Steering Committee prior to the inclusion of a new treatment in the protocol.

Breastfeeding

- WHO recommends breastfeeding should be stopped in a lactating woman with Ebola Disease.
- There may be rare circumstances (e.g. *a concordantly infected child younger than six months old without a safe feeding substitute*) where a woman with a *Filovirus infection continues to breastfeed. These decisions will be made independent of the trial.*
- In the circumstance that a woman continues breastfeeding she would remain eligible for enrolment with any dose modifications specified in virus specific annexes.

Children

- Mortality is higher in children compared to adults with Ebola Disease, but the association between age and death is not certain for Marburg Disease.
- **Children of all ages are eligible for enrolment.**
Modifications for children are described in virus specific annexes

Vaccination

- **Patients will be eligible for enrolment irrespective of whether they have been vaccinated for a filovirus, including the use of experimental vaccines, and vaccines used as post-exposure prophylaxis.**
- Vaccination status, including date and name of vaccine, will be recorded for all patients

- **THANK YOU**