INRB-ANRS 0515s EBO-PEP - Information for participants

Title: **Evaluation of the efficacy of a post-exposure prophylaxis (PEP) strategy in contacts at risk of developing a Filovirus Disease: an adaptive platform trial**

In brief	Coordinating Investigators: Pr Placide Mbala & Dr Marie Jaspard & Pr Pauline Byakika-Kibwika
	Structure/teams: ALIMA, MEREVA, INRB, CERFIG, ANSS, ISGlobal, UCAD, PANTHER, NPHIL, NPHA, INSP, MUST, Inserm
	Start date: 16 July 2026 End date of research: NA
	Number of participants expected: • Subprotocol No. 1 (ODV-BDBV): 998 • Subprotocol No. 2 (RDV-BDBV): 350
	Research status: • Subprotocol No. 1 (ODV-BDBV): Ongoing • Subprotocol No. 2 (RDV-BDBV): Ongoing
	Pathology: Filovirus disease (FVD)
	Sponsorship: National Institute for Biomedical Research (INRB) & Inserm - ANRS MIE
	Funded under: EDCTP3
The project	EBO-PEP is a randomized controlled platform trial designed to evaluate different post-exposure prophylaxis (PEP) strategies among contacts (children, adolescents, adults) at risk of contracting a filovirus disease (FVD) such as Zaire Ebola virus (EBOV), Sudan Ebola virus (SUDV), Bundibugyo Ebola virus (BDBV), or Marburg virus (MARV). Participants are recruited from countries reporting an FVD outbreak and are individually randomized to different intervention arms based on the virus and the available PEP options. Two subprotocols on Bundibugyo Ebola virus disease (BDV) are currently underway: **Subprotocol No. 1 (ODV-BDV):** a double-blind, placebo-controlled, superiority trial with two parallel arms to evaluate the safety and efficacy of Obeldesivir (ODV) compared to placebo in preventing symptomatic Bundibugyo Ebola virus disease (BVD) in participants who have had high-risk exposure. **Subprotocol No. 2 (RDV–BDBV):** a prospective interventional cohort study aimed at providing insights into the efficacy and safety of Remdesivir in preventing symptomatic Bundibugyo Ebola virus disease (BVD) in children under 12 years of age and in pregnant and breastfeeding women who have had high-risk exposure. This cohort allows for the proposal and evaluation of a potentially effective PEP treatment for vulnerable populations who cannot be included in the ODV-BDBV trial.
Latest news	Not applicable yet
Publication references	Not applicable yet

Type of study	Multicenter, multi-epidemic, phase III, comparative, adaptative trial.
Main objectives	To determine whether the investigational PEP strategy, administered as PEP to contacts of confirmed FVD cases, reduce the risk of developing symptomatic PCR-confirmed FVD compared with the control arm over the 21-day incubation window.
Secondary objectives	For all interventional subprotocols: • To determine whether the investigational PEP strategy, administered as PEP to contacts of confirmed FVD cases, reduce the risk of developing symptomatic PCR-confirmed FVD compared with the control arm over 42-days (two incubation period); • To evaluate the safety and tolerability of investigational PEP strategy relative to the control arm.Compare EVD severity between the different trial arms; • To determine whether the investigational PEP strategy reduces the severity of PCR-confirmed FVD, compared with the control arm; • To determine whether the investigational PEP strategy reduces the rate of asymptomatic FVD, compared with the control arm; • To determine whether the investigational PEP strategy reduces mortality, compared with the control arm; • To describe the evolution of viral load across trial arms; • To estimate the cost-effectiveness ratio in the different trial arms; Additional Secondary Objective for Subprotocol No. 1 (ODV-BDBV): To determine whether Obeldesivir, administered as PEP to contacts, reduce the risk of developing symptomatic PCR-confirmed BVD compared with the placebo on the optimal window combining a PEP and a PrEP effect (i.e. 10 to 21 days following randomization). Secondary objectives for Subprotocol No. 2 (RDV-BDBV): Adaptation of the objectives applicable to all subprotocols for the intervention cohort.
Link to research website	www.ebo-pep.com