ANRS 0515s EBO-PEP - Information for participants

Title: **Evaluation of the efficacy of a post-exposure prophylaxis (PEP) strategy in contacts at high risk of developing Ebola virus disease (EVD)**

In brief	Coordinating Investigators: Pr Placide Mbala & Dr Marie Jaspard
	Structure/teams: ALIMA, MEREVA, INRB, CERFIG, ANSS, ISGlobal, UCAD, PANTHER, NPHIL, NPHA, INSP Inserm
	Start dates: Not yet started End date of research: NA
	Number of participants expected: 162
	Research status: To be start
	Pathology: Ebola virus disease (EVD)
	Promotion: Inserm - ANRS MIE
	Funded under: EDCTP3
The project	EBO-PEP is a multi-country and multi-epidemic trial in which high risk contact (children, adolescents, adults) of contracting Ebola virus disease are recruited during an epidemic in several countries (Democratic Republic of Congo, Guinea, Liberia, Sierra Leone). Participants will be randomized (1:1) into one of two arms of the trial: • Ervebo® arm (control arm) ; • Ervebo® + Inmazeb® arm. The hypothesis is that administering Inmazeb® in combination with Ervebo® as PEP in the days following high-risk exposure to EVD will reduce the incidence of EVD within 21 days of administration compared to a PEP strategy using Ervebo® alone.
Latest news	Not applicable yet
Publication references	Not applicable yet
Type of study	Multicenter, multi-epidemic, phase III, comparative, controlled, randomized, one-sided, superiority trial with two parallel, unblinded arms.
Main objectives	Compare the rate of EVD at 21 days in contacts at high-risk of EVD receiving a PEP strategy of ERV+IMZ *vs*. ERV alone.
Secondary objectives	• Compare the rate of EVD at 60 days in contact at high-risk of EVD receiving a PEP strategy with ERV+IMZ versus ERV alone • Compare safety and tolerance between the different trial arms • Compare EVD severity between the different trial arms • Compare the rate of asymptomatic EVD between the different trial arms • Compare the proportion of deaths between the different trial arms • Describe the evolution of viral load in the different trial arms • Estimate the cost-effectiveness ratio in the different trial arms
Link to research website	www.ebo-pep.com