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The INTEGRATE study: An adaptive platform trial for the development of new interventions to combat Lassa Fever in West Africa

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Introduction

Lassa fever (LF) is a viral haemorrhagic fever responsible for thousands of deaths per year in West Africa, with in-hospital mortality at 12%. Ribavirin is the recommended treatment of LF. However, the absence of state-of-the-art intensive care, the questionable effectiveness and the important toxicity of Ribavirin, and the high burden of LF in West Africa call for novel drug therapies.

Methods

The INTEGRATE trial is a multinational, multicentre, controlled, randomized, adaptive phase II-III platform superiority trial with open-label parallel arms. The primary objective is to compare the efficacy of Investigational Medicinal Products (IMPs) regimen to Ribavirin on prevention of death or organ failure in hospitalized adult participants. Participants are hospitalized for at least 10 days, and followed for 28 days. The platform trial evaluates IMP regimen against Ribavirin in phase II and phase III, with adaptative design in phase II depending on the IMP type. The trial is sponsored by the Irrua Specialist Teaching Hospital (ISTH) in Nigeria, with INSERM ANRS MIE, France, as a co-sponsor.

Results

Enrollment has started in May 2025 at the Federal Medical Centre Owo, one of the largest LF treatment center in Nigeria. Next site opening to come will be at ISTH. Currently, the first IMP to be evaluated is the association of Dexamethasone and ribavirin for severe patients. Further recruiting sites across West-Africa (e.g., Liberia, Benin, Guinea, Nigeria) and further IMPs (e.g. favipiravir, ARN 75039) are planned to be added to the platform over the course of the trial. More than 500 participants are expected to join the trial over the coming years.

Conclusion

The ribavirin treatment for LF is still debated in term of safety, efficacy and affordability. The

INTEGRATE study will provide critical evidence on the efficacy of novel therapies, with the goal of improving patient outcomes and alleviating the global burden of LF.