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Safety and tolerability of dexamethasone combined with standard-of-care Ribavirin for the treatment of Lassa fever: An open-label randomized controlled phase II clinical trial

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Introduction

Lassa fever (LF) can progress to severe disease resulting in high mortality. Ribavirin is the standard-of-care antiviral therapy. Dexamethasone, a corticosteroid, modulates inflammation-mediated tissue damage. It is hypothesized that its addition to ribavirin may enhance the effectiveness of LF treatment. This phase II clinical trial evaluated its safety and tolerability.

Methods

This prospective, open-label, randomized controlled phase II clinical trial conducted at a reference hospital in Nigeria assessed the safety and tolerability of adjunct dexamethasone combined with ribavirin compared to ribavirin alone for the treatment of LF. Hospitalized adult participants with PCR-confirmed LF were eligible (n=21 per arm). Safety data were collected over a 10-day follow-up period. Preliminary data will be presented.

Results

Recruitment began in February 2024. As of May 2025, 36 evaluable participants have been included, with 19 (53%) female and median age of 33.5 years (range 19–67). Among the 17 participants receiving ribavirin alone, 14 adverse events (AEs) were reported. Two were graded as severe, dyspnea and Lassa meningitis, both considered as complication of the disease and leading to participant withdrawal due to the need for concomitant steroid therapy. Additionally, one case of severe Lassa fever leading to death was reported as serious adverse event (SAE). Among the 19 participants receiving adjunct dexamethasone, 18 AEs were reported, mostly mild. No severe AEs or SAEs occurred. All participants in the dexamethasone arm completed the 10-day follow-up.

Conclusion

Preliminary findings suggest that adjunct dexamethasone therapy is safe and tolerable. The AE severity tended to be higher in the ribavirin-only

arm. These events were attributed to LF progression, suggesting that dexamethasone may contribute to improved clinical outcomes. These results support the rationale for more extensive evaluation, potentially informing future treatment guidelines and expanding evidence-based options for LF management.