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Title: **Multicenter clinical trial of nifurtimox-eflornithine combination therapy for second-stage sleeping sickness**

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Current therapies for second-stage gambiense human African trypanosomiasis (sleeping sickness) are either toxic or impracticable in field conditions. Most patients are still treated with highly toxic melarsoprol, with failure rates increasing in several foci. Eflornithine, the only alternative, is difficult to implement, and is used in first-line only in a few resource-intensive treatment centers.
We compared the efficacy and safety of a simplified nifurtimox-eflornithine drug combination (i.e. 14 intravenous infusions) to the standard eflornithine regimen (i.e. 56 intravenous infusions) in a randomized, non-inferiority, multicenter trial. Participants were parasitologically confirmed, had more than 20 leukocytes/uL of cerebrospinal fluid and were above 14 years old. The investigational treatment was nifurtimox: 15 mg/kg/day, 8-hourly, for 10 days, plus eflornithine: 400 mg/kg/day, 12-hourly for 7 days (N+E). The active comparator was standard eflornithine: 400 mg/kg/day, 6-hourly for 14 days. Safety assessments included clinical adverse events, hematology and biochemistry monitoring of hepatic and renal functions. Patients were followed-up for 18 months for efficacy assessment.
Between 2003 and 2006, 287 patients were enrolled in 4 sites (Nkayi, Congo; Isangi, Dipumba and Katanda, Democratic Republic of Congo). There were three deaths with eflornithine and one with N+E. Patients suffering severe adverse events were fewer with N+E (14.0% vs. 28.7%; p=0.002). Outstanding adverse events with N+E were nausea/vomiting and with eflornithine neutropenia, infections, fever, diarrhea, hypertension.
Preliminary analysis of safety indicators suggests that N+E is better tolerated than standard eflornithine. Final results and conclusions (efficacy and safety) will be available at the time of the congress.

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