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## **Nifurtimox-eflornithine combination therapy for second-stage *Trypanosoma brucei gambiense* sleeping sickness: a randomized clinical trial in Congo.**

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**BACKGROUND:** Human African trypanosomiasis caused by *Trypanosoma brucei gambiense* is a fatal disease. Current treatment options for patients with second-stage disease are either highly toxic or impracticable in field conditions. We compared the efficacy and safety of the nifurtimox-eflornithine drug combination with the standard eflornithine regimen for the treatment of second-stage disease. **METHODS:** A randomized, open-label, active-control, phase III clinical trial comparing 2 arms was conducted at the Sleeping Sickness Treatment Center, which was run by Medecins Sans Frontieres, in Nkayi, Bouenza Province, Republic of Congo. Patients were screened for inclusion and randomly assigned to receive eflornithine alone (400 mg/kg per day given intravenously every 6 h for 14 days) or eflornithine (400 mg/kg per day given intravenously every 12 h for 7 days) plus nifurtimox (15 mg/kg per day given orally every 8 h for 10 days). Patients were observed for 18 months. The study's outcomes were cure and adverse events attributable to treatment. **RESULTS:** A total of 103 patients with second-stage disease were enrolled. Cure rates were 94.1% for the eflornithine group and 96.2% for the nifurtimox-eflornithine group. Drug reactions were frequent in both arms, and severe reactions affected 25.5% of patients in the eflornithine group and 9.6% of those in the nifurtimox-eflornithine group, resulting in 2 and 1 treatment suspensions, respectively. There was 1 death in the eflornithine arm and no deaths in the nifurtimox-eflornithine arm. **CONCLUSIONS:** The nifurtimox-eflornithine combination appears to be a promising first-line therapy for second-stage sleeping sickness. If our findings are corroborated by ongoing findings from additional sites (a multicenter extension of this study), the new nifurtimox-eflornithine combination therapy will mark a major and multifaceted advance over current therapies.

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