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Amphotericin B treatment for Indian visceral leishmaniasis: response to 15 daily versus alternate-day infusions.

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BACKGROUND: For patients with Indian visceral leishmaniasis, amphotericin B deoxycholate is usually given as 15 alternate-day infusions of 1 mg/kg over 30 days (total dose, 15 mg/kg); daily treatment with 1 mg/kg for 20 days (total dose, 20 mg/kg) is also used. This study was done to address the unsettled therapeutic questions of administration schedule (alternate-day vs. daily administration) and dose (1 vs. 0.75 mg/kg) and to determine whether the duration of amphotericin B treatment in Bihar, India, can be shortened to 15 days. **METHODS:** To compare alternate-day versus daily administration and 1-mg/kg versus 0.75-mg/kg doses and to determine whether the duration of treatment could be abbreviated, Indian subjects randomly received 15 infusions of 1 mg/kg (group A; 245 patients) or 0.75 mg/kg (group B; 244 patients) on alternate days or 1 mg/kg (group C; 500 patients) or 0.75 mg/kg (group D; 496 patients) daily. Noninferiority testing compared 6-month cure rates using a 5% margin. **RESULTS:** Overall, 1439 of the 1485 subjects completed treatment and responded. Treatment interruptions (nephrotoxicity) but not infusion-associated reactions or study removals were more common with daily administration. Final cure rates at 6 months were similar: group A, 234 patients (96%; 95% confidence interval [CI], 92%-98%); group B, 225 patients (92%; 95% CI, 88%-95%); group C, 483 patients (97%; 95% CI, 95%-98%); and group D, 476 patients (96%; 95% CI, 94%-97%; $P > .05$). **CONCLUSIONS:** Provided that the serum creatinine level is repeated once, daily treatment with amphotericin B, 0.75 mg/kg for 15 days (total dose, 11.25 mg/kg), is efficient and effective for visceral leishmaniasis in India. **TRIAL REGISTRATION:** ClinicalTrials.gov identifier: NCT00310505.

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