This Abstract was presented at the 2004 meeting of the American Society of Tropical Medicine and Hygiene. It is the interim analysis of data from the Phase 3 trial of paromomycin in India.

Visceral leishmaniasis (VL) is a commonly fatal parasitic disease affecting 500,000 people annually, primarily in India, Bangladesh, Nepal, Sudan and Brazil. Current treatment options are toxic or expensive; anti-parasitic drugs are increasingly ineffective. The non-profit pharmaceutical Institute for OneWorld Health is developing the off-patent aminoglycoside *paromomycin* as a new, safe, effective, inexpensive cure for VL. A phase 3, randomized clinical trial is being completed at 4 sites in Bihar, India. Aims are to determine the safety of paromomycin compared to amphotericin B and its efficacy at 1 and 6 months after end of treatment. Patients aged 5-55 years with confirmed VL consented to audiometric, HIV and pregnancy testing. Eligible patients were randomized in a 3:1 ratio to receive paromomycin (IM, 15 mg/kg/day for 21 days) or amphotericin B (IV, 1 mg/kg/every other day for 30 days). A total of 667 patients (502 paromomycin, 165 amphotericin B) was enrolled from 6/2003 to 4/2004. Rates of death, withdrawal and overall adverse events (AE) were similar between drugs (paromomycin: 1%, 0.4%, 64%; amphotericin B: 1%, 1%, 67%). However, the mean number of AEs and concomitant medication use were statistically significantly decreased for paromomycin compared to amphotericin B (mean AE number: 1.2 vs. 4.1; medication use: 22% vs. 80%). Primary AEs for paromomycin included pain at injection site (87%) and for amphotericin B, fever/chills/rigor/vomiting (94%). Reversible ototoxocity at 10-12 KHz was observed in 2 paromomycin patients; nephrotoxicity was observed for amphotericin B only (n=1). 6 month follow-up will be completed in 11/2004; 4 week cure rates were 98% for both drugs. In conclusion, initial results suggest that paromomycin is a safe and effective cure for VL in India.