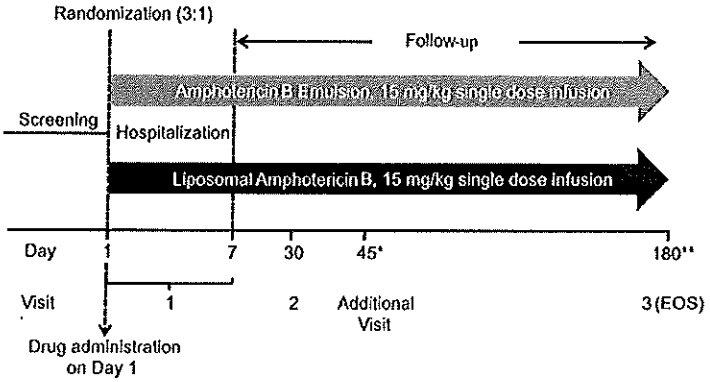
d. **Details of the research work duly signed by the applicant, for which the Sun Pharma Science Foundation Research Award is claimed, including references and illustrations (not to exceed 6000 words)**

The Sun Pharma Science Foundation Research Award is claimed for my following research publications:

- Efficacy and Safety of Amphotericin B Emulsion versus Liposomal Formulation in Indian Patients with Visceral Leishmaniasis: A Randomized, Open-Label Study. Shyam Sundar, **Krishna Pandey**, Chandreshwar Prasad Thakur, Tara Kant Jha, Vidya Nand Ravi Das, Neena Verma, Chandra Shekhar Lal, Deepak Verma, Shahnawaz Alam, Pradeep Das. PLoS Negl Trop Dis. 2014 Sep; 8(9): e3169. Published online 2014 Sep 18. doi: 10.1371/journal.pntd.0003169

India is home to 60% of the total global visceral leishmaniasis (VL) population. Use of long-term oral (e.g. miltefosine) and parenteral drugs, considered the mainstay for treatment of VL, is now faced with increased resistance, decreased efficacy, low compliance and safety issues. The authors evaluated the efficacy and safety of an alternate treatment option, i.e. single infusion of preformed amphotericin B (AmB) lipid emulsion (ABLE) in comparison with that of liposomal formulation (LAmB).

In this multicentric, open-label study, 500 patients with VL were randomly assigned in a 3:1 ratio to receive 15 mg/kg single infusion of either ABLE (N=376) or LAmB (N=124). Initial cure (Day 30/45), clinical improvement (Day 30) and long term definitive cure (Day 180) were assessed.




*Day 45 Visit is only for patients with splenic aspirate score +1 on Day 30.
**Follow-up visit at 6 months after study drug administration (EOS Visit).
EOS: end of study

Study design.

A total of 326 (86.7%) patients in the ABLE group and 122 (98.4%) patients in the LAmB group completed the study. Initial cure was achieved by 95.9% of patients in the ABLE group compared to 100% in the LAmB group (p=0.028; 95% CI: −0.0663, −0.0150). Clinical improvement was comparable between treatments (ABLE: 98.9% vs. LAmB: 98.4%). Definitive cure was achieved in 85.9% with ABLE compared to 98.4% with LAmB. Infusion-related pyrexia (37.2% vs. 32.3%) and chills (18.4% vs. 18.5%) were comparable between ABLE and LAmB, respectively. Treatment-related serious adverse events were fewer in ABLE

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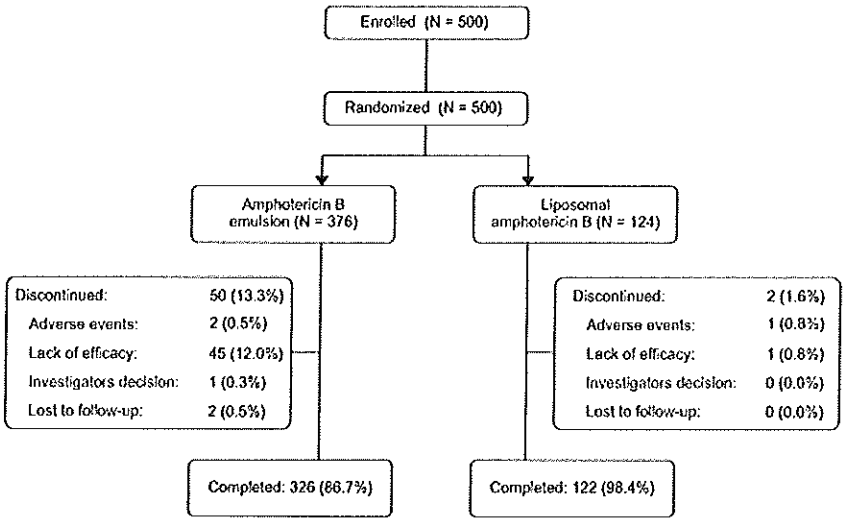
(0.3%) compared to LAmB (1.6%). Two deaths occurred in the ABLE group, of which one was probably related to the study drug. Nephrotoxicity and hepatotoxicity was not observed in either group.




CONSORT patient flowchart.

ABLE 15 mg/kg single infusion had favorable efficacy and was well tolerated. Considering the demographic profile of the population in this region, a single dose treatment offers advantages in terms of compliance, cost and applicability.

- Pharmacovigilance of Miltefosine in Treatment of Visceral Leishmaniasis in Endemic Areas of Bihar, India. **Krishna Pandey**, Vidyanand Ravidas, Niyamat A. Siddiqui, Sanjay K. Sinha, Rakesh B. Verma, Tripurari P. Singh, A. C. Dhariwal, R. K. Das Gupta, Pradeep Das. Am J Trop Med Hyg. 2016 Nov 2; 95(5): 1100–1105. doi: 10.4269/ajtmh.16-0242

Miltefosine, the only oral drug for visceral leishmaniasis (VL), is being used as the first-line drug under the VL elimination program in the Indian subcontinent. Miltefosine is an oral drug which was used as a topical application for skin metastasis of breast cancer. It was found to be effective against *Leishmania donovani*. The main adverse events (AE) reported previously with miltefosine use includes diarrhea, vomiting, and dehydration. Other AEs include, raised serum alanine transaminase/aspartate aminotransferase and renal parameters such as creatinine. In this study, we report AEs in a large patient cohort of VL treated with miltefosine. The purpose of this pharmacovigilance study was to assess adverse drug reactions (ADRs)/AE of miltefosine treatment under unrestricted condition in the field setup. Patients were followed up to 6 months for therapeutic effectiveness. Outcomes of a larger data set of patients treated with this regimen from April 2012 to March 2015 were recorded.

An open-label, single-arm trial was designed to investigate the safety and efficacy of miltefosine in the treatment of VL patients under unrestricted condition in the field setup.

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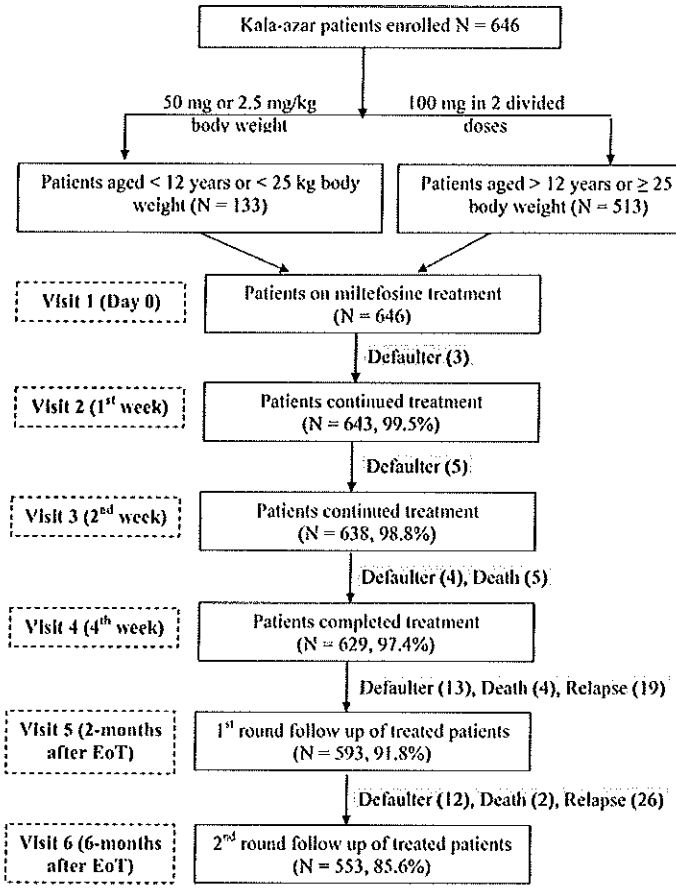


Treatment compliance chart.

A total of four sentinel sites in the highly endemic districts of Bihar were selected as per the readiness criteria like availability of recombinant kinesin-39 (rk-39) for VL diagnosis, use of miltefosine for VL treatment, availability of health personnel and other infrastructure needed for proper health delivery, etc. The identified sites included two district hospitals—East Champaran and Samastipur Districts and two primary health centers—Paroo of Muzaffarpur and Baniyapur of Saran District of Bihar.

In the present study, 646 patients of VL were given miltefosine. Majority of the study subjects (58%) were male. Relapse occurred in 7% during follow-up period. Main causes of death were VL–pulmonary tuberculosis coinfection, extreme diarrhea, and acute pancreatitis which were reported in 1.7% subjects. Of 553 (85.6%) patients completing full course of treatment, 463 (83.7%) showed ADR with miltefosine during the study period. About 2.3% were suffering severe ADR, 51% from moderate, and the rest had mild ADR. The initial and final cure rate was 97.4% and 85.6%, respectively. Miltefosine has been found to be very effective and extremely safe for use in adults. However, because of long half-life, it can be a candidate for development of resistance. It is the number one drug for treatment of PKDL as per NVBDCP guidelines as well. No side effects of miltefosine in pregnant women reported in this study attracts a comprehensive study to establish its use in pregnant women or women of child-bearing age without use of contraceptive measures.

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