

Safety and Efficacy of Oral Miltefosine for the Treatment of Cutaneous Leishmaniasis: A Prospective Cohort Study

Shimelis Doni

Cutaneous leishmaniasis (CL) lacks effective treatment options, especially in Ethiopia. Miltefosine offers an oral alternative, but efficacy for 28 days treatment was limited and there are concerns about potential ocular complications. A prospective observational cohort study was conducted on patients treated with miltefosine for 28-56 days at treating physicians' discretion. Children received allometric dosing, adults 150 or 100mg based on bodyweight. Clinical improvement was evaluated during treatment at day 28 and after treatment at day 90 and day 180. Cure was complete flattening and re-epithelization of all lesions, while substantial improvement was defined as at least 51% improvement. Ocular evaluations were done at the beginning and end of treatment. The cohort included 77 CL patients, 37 children receiving allometric dosing and 40 adults. The majority (69/77, 89%) received 56 days of treatment. At day 28, 75/77 (97.4%) of patients had substantial improvement. Cure rate was 18/65 (27.7%) at day 90 which increased to 55.6% (25/45) at day 180. Cure rates were 5/13 (38.5%) for children receiving allometric dosing and 20/32 (62.5%) for adults. The majority of patients (64/77, 83.1%) had AEs, mostly gastro-intestinal and mild. One patient had elevated ocular pressure as potential ocular complication, which resolved after stopping miltefosine. By reporting time, 89.38% of AEs had resolved, mostly without intervention. Miltefosine leads to clinical improvement in almost all patients after 28 days, but many patients do not complete cure despite treatment extension. Side effects are common but mild. Our findings suggest treatment optimization is needed, especially for children.

Dr Shimelis Nigussie Doni is a consultant dermato-venereologist at ALERT Comprehensive Specialised Hospital in Addis Ababa, Ethiopia, with a strong commitment to both medical research and clinical care. His work focuses on skin neglected tropical diseases (NTDs), particularly leprosy and cutaneous leishmaniasis, and he has authored and co-authored numerous scientific publications in these fields.

He served as Head of Dermatology and Venereology at ALERT Hospital for 11 years and currently holds leadership positions as President of the Ethiopian Dermatology and Venereology Society (EDVS) and Vice-President of the African Society of Dermatology and Venereology (ASDV). In addition to his institutional responsibilities, he has volunteered as a clinician with an international mobile dermatology clinic in North Shewa, Ethiopia.

Dr Shimelis' contributions have been recognised internationally, including receiving the Best E-Poster Presentation Young Scientist Award at the International Leprosy Congress in Brussels (2013). He is also an active member of ENLIST, the Erythema Nodosum Leprosum International Study Group.

His special interests include leprosy, cutaneous leishmaniasis, lymphatic filariasis, onchocerciasis and scabies, reflecting his dedication to advancing dermatological care and addressing pressing global health challenges. His ambition is to improve access to dermatology care in Ethiopia and other developing countries.

