

Failure of an innovative low-cost, non-invasive thermotherapy device in treating cutaneous leishmaniasis in Pakistan

*Suzette Kämink¹, Ahmed Abdi¹, Jena Fernhout², Charity Kamau², Shakil Ashraf³, Naveeda Qureshi⁴, Koert Ritmeijer²

¹Médecins Sans Frontières (MSF), Quetta, Pakistan; ²MSF, Amsterdam, The Netherlands;

³Mohtama Shaheed Benazir Bhutto Hospital, Quetta, Pakistan; ⁴Quaid-i-Azam University, Islamabad, Pakistan

*s.s.kamink@gmail.com

Introduction

Cutaneous leishmaniasis (CL), a neglected tropical skin disease, is endemic in Pakistan, where *Leishmania tropica* and *L. major* are the causative *leishmania* species. Since 2008, MSF has provided diagnostic and treatment services for CL in Quetta, Pakistan. Standard treatment with antimonial injections is long, painful, costly, has toxic side effects, and is not always available in Pakistan's public hospitals. Small pilot studies in Peru, Pakistan, and Syria have previously evaluated a new low-cost and non-invasive treatment, Hand-held Exothermic Crystallisation Thermotherapy for Cutaneous Leishmaniasis (HECT-CL). We aimed to further establish the effectiveness, safety and feasibility of HECT-CL.

Methods

We carried out a prospective observational study within the Benazir Bhutto Hospital in Quetta. CL patients with parasitological confirmation of their lesions were treated using the HECT-CL for 3 minutes with an initial temperature of 52-53°C, for 7 days. 30 dry blood spot samples were taken for species identification using PCR. At baseline, age, sex and village of the patient, and the type, size and location of the lesion(s) and the number of lesions were collected. To assess effectiveness, photographs of the lesions were taken and size (in diameter) was measured at baseline and subsequent follow up visits, for up to 180 days. We intended to enroll 317 patients.

Ethics

This study was approved by the MSF Ethics Review Board and the Pakistan Health Research Council. ClinicalTrials.gov number NCT03208543.

Results

Two months after study start, enrolment of patients was suspended due to futility. Preliminary results once 56 patients had been enrolled showed a failure rate of 92.6% at follow up (median 40 days after treatment, IQR 30 days). Patients in whom HECT-CL failed received rescue treatment with antimonial injections. Of the 30 laboratory samples sent for PCR, 8 were negative and 22 were positive for *L. tropica*. The HECT-CL treatment was well tolerated. 11 patients (20%) developed secondary infections in the follow up period. Health workers reported that HECT-CL was easy to use, but time consuming.

Conclusion

This study showed a high failure rate for HECT-CL thermotherapy in this setting. A plausible reason for the failure is the difference in *Leishmania* species. *L. tropica* was found in this study, while *L. major* was likely to be the causative species in the previous successful pilot study in Pakistan. *L. tropica*, the predominant species in Baluchistan, is known to be less sensitive to anti-leishmanial drugs and more temperature-resistant. More research is needed to identify low-cost, effective treatments for *L. tropica*.

Conflicts of interest

None declared.

Suzette Kämink

Suzette is originally from the Netherlands; she had studied Cultural Anthropology, but then retrained as an oncology nurse and infectious diseases and public health nurse. After a few years with MSF, she decided to change her career path to medical research and epidemiology, and gained her Master's in Health Sciences, specialising in tropical infectious diseases and public health. From there, Suzette was able to develop a specific interest in leishmaniasis, which she furthered during work in South Sudan. From there, she worked with Koert Ritmeijer on the current study in cutaneous leishmaniasis.

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