

# **Mycobacterium Vaccine Clears Distant as Well as Injected Warts**

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By Anne Harding

NEW YORK (Reuters Health) Mar 05 - Injecting Mycobacterium w (Mw) vaccine directly into cutaneous warts helps clear not just those warts but distant lesions as well, a small open-label study demonstrates.

"Mw vaccine has a very strong immunomodulatory effect. It may be a very viable option in cases with recurrent and extensive warts," coauthor Dr. Amit Malhotra of SMS Medical College in Jaipur, India told Reuters Health. However, he added, a randomized controlled trial with a larger number of patients will be needed before it could be considered a front-line treatment.

The vaccine, IMMUVAC, developed by Cadila Pharmaceuticals and licensed by the National Institute of Immunology in New Delhi, is typically used to treat multibacillary leprosy. Dr. Malhotra had previously found a nearly 90% cure rate in patients with genital warts treated with the vaccine in an open-label, pilot study which he reported in 2008 in the Journal of the European Academy of Dermatology and Venereology.

"Therefore, we decided to evaluate it in the treatment of multiple cutaneous warts," he told Reuters Health in an e-mail interview.

The researchers enrolled 40 patients with three or more cutaneous warts in the current study, which was published as a Research Letter in the February issue of JAMA Dermatology. At baseline, patients received a 0.1 mL dose of the vaccine in each deltoid. Two weeks later, the researchers injected the vaccine into three to five randomly chosen lesions, and they continued to do so every week until the warts were completely cleared or the patients received 10 injections (12 weeks).

Three patients were lost to follow-up. Thirty-three patients (83%) had complete clearance of warts, one had 50% clearance, and the three remaining patients had 25% to 30% clearance. On average, lesions were cleared within 9.7 weeks.

Among the 33 patients with complete wart clearance, 23 also had clearance of distant warts that were not injected; the remaining 10 patients had received injections in all of their warts. Three patients developed recurrence during follow-up lasting an average of about 4.5 months.

All of the patients developed papules and/or pustules at the site of the sensitization injection, which healed but left a small scar. The most common adverse effect was erythema in treated warts, which occurred in 25 patients. Six patients developed swelling and one patient developed superficial ulceration.

Two patients developed low-grade fever with no systemic symptoms on the day they received intralesional injections, starting with their fourth treatment, which lasted only for that day. Two patients who had injections in facial lesions developed swollen submandibular lymph nodes. These patients recovered completely after treatment was discontinued for two weeks and they received five days of treatment with amoxicillin/clavulanic acid.

Based on the findings, Dr. Malhotra said, a randomized controlled trial with a larger number of patients is warranted.

Dr. Adam Friedman, director of dermatologic research at Montefiore Medical Center in New York City, agreed. "The results are definitely worthy of further investigation," Dr. Friedman told Reuters Health.

"They're not reinventing the wheel, they're just adding something to our armamentarium of immunotherapies," he added. Dr. Friedman has studied immunotherapy for warts but did not participate in Dr. Malhotra's study.

The vaccine used in the current study is not available for use in the U.S., Dr. Friedman noted, and he added that the weekly dosing schedule the researchers used might present practical difficulties.

"I would love to see a larger study where the dosing regimen was more practical to what we would use on a day-to-day basis," he added. The ideal, he added, would be a comparison study using other treatments. "To me if they showed equivalent efficacy to cryotherapy, liquid nitrogen, that would be enough."