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Imiquimod in combination with meglumine antimoniate for cutaneous leishmaniasis: A randomized assessor-blind controlled trial

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Abstract

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Objective: To determine the efficacy and safety of imiquimod in combination with meglumine antimoniate in treating cutaneous leishmaniasis. **Design:** Prospective, randomized, assessor-blind, parallel-design, placebo-controlled trial. **Setting:** Two primary care health clinics. **Patients:** One hundred nineteen patients (59 patients in the imiquimod group and 60 in the placebo group) were included in the study. **Interventions:** Patients were randomly assigned to receive a combined 4-week course of imiquimod or placebo with meglumine antimoniate treatment (20 mg/kg of pentavalent antimony daily for 2 weeks) in an endemic area of *Leishmania tropica*. **Main Outcome Measures:** The primary end point was clinical cure, defined as more than 75% reduction in the size of lesions compared with baseline at week 8. **Results:** At the end of the 4-week treatment period, clinical cure was similar in both groups (11 patients [18.6%] in the imiquimod-treated group vs 18 patients [30.0%] in the placebo group) ($P=.15$). Four weeks after the end of treatment, 26 patients (44.1%) and 29 patients (48.3%) in the imiquimod-treated and placebo groups, respectively, were cured ($P=.64$). Pruritus and burning sensation were reported by 3 patients treated with imiquimod and by no patients treated with placebo. **Conclusion:** This study showed no beneficial effect of combining a 4-week course of treatment with 5% imiquimod cream and a standard course of treatment with meglumine antimoniate in patients with cutaneous leishmaniasis in an endemic area of *L. tropica*. ©2006 American Medical Association. All rights reserved.

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Indexed Keywords

EMTREE drug terms: imiquimod; meglumine antimoniate; placebo

EMTREE medical terms: adolescent; adult; article; burning sensation; clinical practice; clinical trial; controlled clinical trial; controlled study; drug efficacy; drug safety; drug withdrawal; endemic disease; female; health center; human; major clinical study; male; priority journal; prospective study; pruritus; randomized controlled trial; skin leishmaniasis; treatment duration; treatment response

MeSH: Adjuvants, Immunologic; Adolescent; Adult; Aminoquinolines; Animals; Antimony; Antiprotozoal Agents; Child; Drug Therapy, Combination; Female; Follow-Up Studies; Humans; *Leishmania tropica*; Leishmaniasis, Cutaneous; Male; Meglumine; Middle Aged; Organometallic Compounds; Prospective Studies; Single-Blind Method; Treatment Outcome
Medline is the source for the MeSH terms of this document.

Chemicals and CAS Registry Numbers: imiquimod, 99011-02-6; meglumine antimoniate, 133-51-7; Adjuvants, Immunologic; Aminoquinolines; Antimony, 7440-36-0; Antiprotozoal Agents; Meglumine, 6284-40-8; Organometallic Compounds; imiquimod, 99011-02-6; meglumine antimoniate, 133-51-7

Drug tradename: aldara, 3M, France; glucantime, Rhodia, France.

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