Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Imiquimod in Combination With Meglumine Antimoniate for Cutaneous Leishmaniasis: A Randomized Assessor-Blind Controlled Trial

Protocol summary

Summary

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: 90 (Forty-five patients per treatment group) were included in the study. Inclusion criteria: (1) parasitologically proven cases of CL based on positive smear or culture (2) otherwise healthy subjects (3) age 12 to 60 years (4) willingness to participate in the study and sign the informed consent (by the patient or his or her parent or guardian in patients younger than 18 years) Exclusion criteria: (1) pregnant or lactating women, (2) duration of lesions longer than 6 months (3) number of lesions more than 5 (4) any lesions larger than 5 cm (5) history of any standard course of treatment with antimonials (6) history of allergy to antimonials (7) serious systemic illnesses (as judged by the physician) (8) participation in any drug trials in the last 60 days. 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.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706111166N1**
Registration date: **2008-10-21, 1387/07/30**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2008-10-21, 1387/07/30

Registrant information

Name
Alireza Khatami
Name of organization / entity
Center for Research and Training in Skin Diseases and Leprosy, Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Grants Scheme for Operational Research in Tropical and Other Communicable Diseases from the Joint World Health Organization Eastern Mediterranean Region Division of Communicable Diseases and the Special Program for Research and Training in Tropical Diseases. The MA was provided by the Iran Ministry of Health.

Expected recruitment start date

2004-08-01, 1383/05/11

Expected recruitment end date

2005-07-25, 1384/05/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Imiquimod in Combination With Meglumine Antimoniate for Cutaneous Leishmaniasis: A Randomized Assessor-

Blind Controlled Trial

Public title
Imiquimod in Combination With Meglumine Antimoniate for Cutaneous Leishmaniasis: A Randomized Assessor-Blind Controlled Trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: (1) parasitologically proven cases of CL based on positive smear or culture (2) otherwise healthy subjects (3) age 12 to 60 years (4) willingness to participate in the study and sign the informed consent (by the patient or his or her parent or guardian in patients younger than 18 years) Exclusion criteria: (1) pregnant or lactating women, (2) duration of lesions longer than 6 months (3) number of lesions more than 5 (4) any lesions larger than 5 cm (5) history of any standard course of treatment with antimonials (6) history of allergy to antimonials (7) serious systemic illnesses (as judged by the physician) (8) participation in any drug trials in the last 60 days.
Age
From **12 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
isrctn.org
Secondary trial Id
ISRCTN77659407
Registration date
2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee
Name of ethics committee
Center for Rresearch and Training in Skin Diseases and Leprosy, Tehran University of Medical Science
Street address
No. 79, Taleqani Avenue
City
Tehran
Postal code
14166-13675
Approval date
2003-09-01, 1382/06/10
Ethics committee reference number
1082/423/ج

Health conditions studied

1

Description of health condition studied
Cutaneous leishmaniasis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
clinical cure(more than 75% reduction in the size of lesions compared with baseline)
Timepoint
Baseline - Weeks 4 and 8
Method of measurement
Measurement of induration, ulcer and erythema size with a ruler.

Secondary outcomes

1

Description
Adverse effects
Timepoint
Baseline - Weeks 4 and 8
Method of measurement
Medical history taking and physical examination

2

Description
clinical improvement (50%-75% reduction in the size of lesions compared with the baseline)
Timepoint
Baseline - Weeks 4 and 8
Method of measurement
Measurement of the size of induration, ulecr and erythema of the lesion(s) with a ruler

Intervention groups

1

Description
20 mg/kg/d of pentavalent antimony (Glucantime [equivalent to 60 mg/kg of MA]; Rhodia Laboratories, Rhone-Poulenc, France) given as intramuscular injections for 14 days+ 5% imiquimod cream (Aldara;Laboratoires 3M Sante´, Cergy Pontoise, France) 3 times a week
Category
Treatment - Drugs

2

Description
20 mg/kg/d of pentavalent antimony (Glucantime [equivalent to 60 mg/kg of MA]; Rhodia Laboratories, Rhone-Poulenc, France) given as intramuscular injections for 14 days+ Placebo(petrolatum; Paveh Pharmaceuticals, Paveh, Iran) 3 times a week)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Eedgah and Ab-obargh clinics
Full name of responsible person
Alireza Firooz, MD
Street address
City
Mashad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
the Joint World Health Organization Eastern Mediterranean Region Division of Communicable Diseases
Full name of responsible person
-
Street address
-
City
-
Grant name
گرانتهاي كوچك براي تحقيقات عملياتي در بيماريهاي گرمسير و سرايت پذير
Grant code / Reference number
SGS03/18
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
the Joint World Health Organization Eastern Mediterranean Region Division of Communicable Diseases
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Center for Research and Training in Skin Diseases and Leprosy, Tehran University of Medical Sciences
Full name of responsible person
Alireza Firooz, MD
Position
Associate Professor of Dermatology
Other areas of specialty/work
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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty