

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 21 8897 0657

Email address

akhatami@tums.ac.ir

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/ع

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

گزارشهای کوچک برای تحقیقات عملیاتی در بیماریهای گرمسیر و سرایت پذیر

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

Street address

No. 79, Taleqani Avenue

City

Tehran

Postal code

14166-13675

Phone

+98 21 8897 8190

Fax

+98 21 8896 3804

Email

firozali@sina.tums.ac.ir

Web page address

Person responsible for scientific 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

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Web page address

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