

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of the efficacy of the combination of a silver-containing dressing with intralesional meglumine antimoniate injections in comparison with a combination of an inert dressing and intralesional meglumine antimoniate injections and intralesional meglumine antimoniate injections alone in the treatment of cutaneous leishmaniasis due to *Leishmania major*: A randomized assessor-blind controlled clinical trial

Protocol summary

Summary

Aim: This study is designed to assess the efficacies of combinations of intralesional injections of meglumine antimoniate (MA) and a silver dressing, intralesional MA and an inert dressing in comparison with the intralesional injections of MA in the treatment of CL due to *L. major*.
Study design: Randomized, assessor-blind controlled clinical trial. **Duration and Place:** 12 months-Kashan
Sample size: 120 patients (40 patients in each group) (210 lesions: 70 lesions in each group) **Interventions:** Group 1: combination of a silver-containing dressing (to be changed every other day) and weekly intralesional meglumine antimoniate injections for 6 weeks; Group 2: combination of an inert dressing (to be changed every other day) and weekly intralesional meglumine antimoniate injections for 6 weeks; Group 3- weekly intralesional meglumine antimoniate injections alone for 6 weeks. **Inclusion and exclusion criteria:** Inclusion criteria: a) Parasitologically proven cases of cutaneous leishmaniasis b) Otherwise healthy c) Age: 12-60 years d) willing to participate in the study. Exclusion criteria: a) Pregnant or lactating women b) Duration of lesions more than 3 months c) Number of lesions more than 5 d) Ulcer size greater than 5 cm in the largest diameter e) History of full course of standard treatment (antimonials) f) Indication for administration of systemic treatment with meglumine antimoniate g) Presence of secondary bacterial infection of the lesion according to clinical appearance of the lesion. **Primary outcome:** Complete healing of the lesions 6 weeks after the initiation of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138707201166N2**
Registration date: **2008-10-21, 1387/07/30**
Registration timing: **registered_while_recruiting**

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

Tehran University of Medical Sciences

Expected recruitment start date

2008-09-09, 1387/06/19

Expected recruitment end date

2009-09-09, 1388/06/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the efficacy of the combination of a silver-containing dressing with intralesional meglumine antimoniate injections in comparison with a combination of an inert dressing and intralesional meglumine antimoniate injections and intralesional meglumine antimoniate injections alone in the treatment of cutaneous leishmaniasis due to Leishmania major: A randomized assessor-blind controlled clinical trial

Public title

Assessment of the efficacy of dressings in the treatment of cutaneous leishmaniasis due to Leishmania major: A randomized, single-blind controlled clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: a) Parasitologically proven cases of cutaneous leishmaniasis based on positive smear and/or culture b) Otherwise healthy subjects on the basis of medical history c) Age: 12-60 years d) willing to participate in the study and sign the informed consent (by the patient or his/her/partner/guardian) in case of younger than 18 years Exclusion criteria: a) Pregnant or lactating women b) Duration of lesions more than 3 months c) Number of lesions more than 5 d) Ulcer size greater than 5 cm in the largest diameter e) History of full course of standard treatment (antimonials) f) History of allergy to meglumine antimoniate or silver g) Serious systemic illnesses as judged by the physician h) Participation in any drug trial in the last 60 days i) Indication for administration of systemic treatment with meglumine antimoniate j) Presence of secondary bacterial infection of the lesion according to clinical appearance of the lesion

AgeFrom **12 years** old to **60 years** old**Gender**

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **210****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

Cochrane Skin Group

Secondary trial Id

CSG Trial No. 51

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee of the Center for Research and Training in Skin Diseases and Leprosy, Tehran Unive

Street address

No. 79, Taleqani Avnue

City

Tehran

Postal code

12675-14166

Approval date

2007-11-30, 1386/09/09

Ethics committee reference number

1625/423/ع

Health conditions studied**1****Description of health condition studied**

Cutaneous leishmaniasis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Complete healing

Timepoint

at 6 weeks after initiation of the intervention(s)

Method of measurement

Lesions' assessment of healing by measuring the size of induration and ulcer

Secondary outcomes**1****Description**

Complete healing

Timepoint

at 6 months after initiation of the intervention(s)

Method of measurement

Lesions' assessment of healing by measuring the size of induration and ulcer

2**Description**

Adverse Effects

Timepoint

Recorded at each follow-up visit

Method of measurement

Taking medical history and performing physical examination

Intervention groups**1****Description**

Group 1-Weekly intralesional injection of meglumine antimoniate (Glucantime, Rhodia Laboratories, rhone Polenc, France) up to six consecutive weeks or complete healing of the lesion Group/2-Weekly intralesional injection of meglumine antimoniate (Glucantime, Rhodia Laboratories, Rhone Polenc, France) up to six consecutive weeks or complete healing of the lesion plus every other day application of an inert dressing (Atrauman, Hartmann CMC Consumer Medical Care GmbH, Heidenheim, Germany) on each lesion for six consecutive weeks or complete healing/Group 3-Weekly intralesional injection of meglumine antimoniate up to six consecutive weeks or complete healing of the lesion plus every other day application of a silver containing (Atrauman Ag, Hartmann CMC Consumer Medical Care GmbH, Germany, Heidenheim, Germany) dressing on each lesion for six consecutive weeks or complete healing

Category

empty

Recruitment centers**1****Recruitment center****Name of recruitment center**

Golabchi Clinic

Full name of responsible person

Alireza Firooz, MD

Street address

Imam Khomeini Street

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Kashan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooz, MD

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Center for Research and Training in Skin Diseases and Leprosy, No.79, Taleqani Avenue

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Tehran

Grant name**Grant code / Reference number**

Project number: 87/01/03/6766-Contract number 132/344

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

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

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Position

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Other areas of specialty/work**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