Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Efficacy of Topical Liposomal Amphotericin B versus Intralesional Meglumine Antimoniate (Glucantime) in the Treatment of Cutaneous Leishmaniasis

Protocol summary

Summary

This study is designed to compare the therapeutic effects of a formulation of topical liposomal Amphotricin B with intralesional Meglumine Antimoniate (Gllucantime) in the treatment of cutaneous Leishmaniasis due to Leishmania Tropica. 110 patients (55 patients in each group) with cutaneous leishmaniasis approved by either a direct smear stained with Giemsa or a positive skin biopsy of lesions with less than 6 months duration were enrolled in a randomized, single-blind controlled trial done during a 24-month period in Mashhad. The first group received liposomal Amphotericin B, 3-7 drops twice daily, according to the size of lesion, for 8 weeks. The second group received intralesional glucantime once a week, to the point when the surface of lesion became fully infiltrated (up to a maximum dose of 2 ml for 8 weeks). The treatment period was 8 weeks for each group and the patients are followed up every two weeks during the treatment course and the changes in the size of lesion and induration were recorded in every session. The primary outcome measure was complete healing of cutaneous leismaniasis lesion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138802131871N1**
Registration date: **2009-09-26, 1388/07/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-09-26, 1388/07/04

Registrant information

Name

Pouran Layegh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research Council of Mashhad University of Medical Sciences

Expected recruitment start date

2004-09-10, 1383/06/20

Expected recruitment end date

2006-09-10, 1385/06/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Topical Liposomal Amphotericin B versus Intralesional Meglumine Antimoniate (Glucantime) in the Treatment of Cutaneous Leishmaniasis

Public title

Comparing efficacy of two treatment methods including topical liposomal Amphotericin B versus intralesional Meglumine Antimoniate (Glucantime) in the Treatment of Cutaneous Leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of cutaneous leishmaniasis approved by either a direct smear stained with Giemsa or a positive skin biopsy of lesions with less than 6 months duration, in cases of previous history of anti-leishmania therapy, a 3 month treatment free interval from the last treatment course Exclusion criteria: Pregnancy, breast feeding, taking any other specific treatment while participating in the study, past medical history of any local or systemic disease during the last 2 months, presence of significant underlying disease such as cardiac, renal or liver dysfunction

Age

From **2 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **110**

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

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashad University of Medical Sciences

Street address

Central Building of Mashad University of Medical Sciences, Mashad, Iran

City

Mashad

Postal code

Approval date

2004-08-10, 1383/05/20

Ethics committee reference number

1803-ت

Health conditions studied

1

Description of health condition studied

Cutaneous leishmaniasis

ICD-10 code

B55.1

ICD-10 code description

Cutaneous Leishmaniasis

Primary outcomes

1

Description

Complete healing

Timepoint

First time within 8 weeks after beginning of treatment and second one after 6 months after initiation of the intervention(s)

Method of measurement

Measuring the size of induration and ulcer

Secondary outcomes

1

Description

Adverse Effects

Timepoint

Recorded at each follow-up visit

Method of measurement

Taking medical history and performing physical examination

Intervention groups

1

Description

Multilamellar Large Vesicle (MLV) liposomes containing Amphotricin B, prepared by freeze drying method, 3-7 drops twice-daily, according to the lesion's size for 8 weeks or complete healing of the lesion.

Category

Treatment - Drugs

2

Description

Intralesional glucantime (Specia®, France) once a week, to the point when the lesion’s surface became fully infiltrated, up to a maximum dose of 2 ml for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Cutaneous Leishmaniasis, Research Center of

Skin Disease and Cutaneous leishmaniasis, Qaem

Full name of responsible person

Dr Poura Layegh, Dr Parisa Emamgholi -Tabar Malekshah

Street address

Qaem Hospital, Ahmad Abad Avenu

City

Mashad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Mashhad University of Medical Sciences

Full name of responsible person

Research Council of Mashhad University of Medical Sciences

Street address

Central Building of Mashad University of Medical Sciences, Mashad, Iran

City

Mashad

Grant name

Grant code / Reference number

1803-ت

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

Yes

Title of funding source

Research Council of Mashhad 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

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Full name of responsible person

Dr Pouran Layegh

Position

Associate Professor of Dermatology

Other areas of specialty/work

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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