

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Pilot study of efficacy of topical nano-liposomal meglumine antimoniate (Glucantime) or paromomycin in combination with systemic Glucantime for the treatment of anthroponotic cutaneous leishmaniasis (ACL) caused by Leishmania tropica

Protocol summary

Summary

Systemic or intralesional pentavalent antimonials are still the first-line treatment of Cutaneous Leishmaniasis (CL). Antimonials are not always effective especially in Anthroponotic CL (ACL), caused by *Leishmania tropica*, patients and resistance is reported. Therapeutic strategy with high efficacy is urgently needed especially for ACL. In this study the efficacy of liposomal formulation of Paromomycin or liposomal formulation of Glucantime in combination with systemic Glucantime in the treatment of ACL parasitologically proven patients will be evaluated. Liposomes, in proper formulations and sizes, deliver drugs to the skin based on the similarity of the bilayers structure of lipid vesicles to that of natural membrane and target the macrophages within dermis. Male or female aged between 12 to 60 years with active lesions will include in the study. Inclusion criteria are parasitologically proven cases of CL and a history of failure to at least one full course of systemic Glucantime. Exclusion criteria are pregnancy or lactating women and duration of lesion less than 12 months. The efficacy of 3 weeks treatment with intramuscular injections of 60 mg/kg/day Glucantime in combination with 4 weeks treatment with topical nano-liposomal paromomycin or glucantime applied, twice daily, or placebo in the treatment of ACL in a randomized, double blind, placebo controlled clinical trial will be assessed. The patients will be followed upto 6 months after the initiation of the treatment. Complete cure equal to complete re-epithelization of all lesions will be the primary outcome of this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809051475N4**

Registration date: **2009-11-26, 1388/09/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2009-11-26, 1388/09/05

Registrant information

Name

Ali Khamesipour

Name of organization / entity

Center for Research and Training in Skin Diseases and Leprosy, Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

1. Vice Chancellor of Research, Mashhad University of Medical Sciences, Mashhad, Iran 2. Center for Research and Training in Skin Diseases and Leprosy, Tehran University of Medical Sciences, Tehran, Iran

Expected recruitment start date

2009-11-30, 1388/09/09

Expected recruitment end date

2010-07-28, 1389/05/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pilot study of efficacy of topical nano-liposomal meglumine antimoniate (Glucantime) or paromomycin in combination with systemic Glucantime for the treatment of anthroponotic cutaneous leishmaniasis (ACL) caused by Leishmania tropica

Public title

Efficacy of Topical Liposomal Glucantime or Paromomycin in Combination With Systemic Glucantime for the Treatment of ACL

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Male or female aged between 12 to 60 years. 2. Parasitologically proven CL due to L. tropica. 3. History of failure to at least one full course of systemic Glucantime. 4. In general good health based on history and physical examination. 5. Number of lesion at most 4. 6. Lesion size less than 3 cm. 7. Signed informed consent voluntarily and knowingly**. ** Guardian's signature for volunteer less than 18 years old. Exclusion criteria: 1. Pregnant or lactating women and those who are planning to be pregnant in next 60 days. 2. Use of other types of treatment for CL. 3. Involvement in any other drug or vaccine trial during the study period. 4. Known heart, kidney, liver diseases based on history and physical exam. 5. Abnormal ECG

Age

From **12 years** old to **60 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

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

Clinicaltrials.gov

Secondary trial Id

NCT01050777

Registration date

empty

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

Mashhad university of medical sciences

Street address

Ghorshi building, Daneshgah Ave.

City

Mashad

Postal code**Approval date**

2009-11-24, 1388/09/03

Ethics committee reference number

454408

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

Protozoal diseases

ICD-10 code

B55.1

ICD-10 code description

Cutaneous Leishmaniasis

Primary outcomes**1****Description**

Complete cure equal to Complete Re-epithelization of all lesions

Timepoint

weekly

Method of measurement

Taking digital pictures

Secondary outcomes

empty

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

Intervention: Systemic glucantime 60 mg/kg/day for 21 days with topical liposomal glucantime twice a day for 28 days

Category

Treatment - Drugs

2**Description**

Intervention: Systemic glucantime 60 mg/kg/day for 21 days with topical liposomal paromomycine twice a day

for 28 days

Category

Treatment - Drugs

3

Description

Control: Systemic glucantime 60 mg/kg/day for 21 days with topical placebo twice a day for 28 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin disease and Cutaneous leishmaniasis research center, MUMS

Full name of responsible person

Dr Masoud Maleki

Street address

Ghaem Hospital

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical sciences

Full name of responsible person

vice-chancellor for reseach

Street address

Ghorshi building, Daneshgah Ave.

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Tehran University of medical sciences

Full name of responsible person

vice-chancellor for reseach

Street address

Center for Research & Training in Skin Diseases & Leprosy, #79 Taleghani Ave, Tehran, 14166

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Tehran

Grant name

Grant code / Reference number

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

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

School of pharmacy, MUMS

Full name of responsible person

Dr Mahmood reza Jaafari

Position

Professor/PhD

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School of pharmacy, MUMS

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School of pharmacy

City

Mashhad

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*