Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Country

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

City

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

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Position

Professor/PhD

Other areas of specialty/work

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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