Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Double blind, randomized clinical trial on efficacy of combination of meglumine antimoniate (Glucantime) and topical nano-liposomal paromomycin for the treatment of anthroponotic cutaneous leishmaniasis (ACL) caused by Leishmania tropica

Protocol summary

Summary

Pentavalent antimonials, which are still the WHO first-line treatment for Cutaneous Leishmaniasis (CL), requires multiple injections and are painful; as such, not tolerated by most of the patients resulted in low compliance, moreover antimonials are not always effective especially in Anthroponotic CL (ACL) patients. In addition, resistance to pentavalent antimonials has been reported. In this study 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 10 % paromomycin (Lip-PM) applied, twice daily, or placebo in the treatment of ACL in a randomized, double blind, placebo controlled clinical trial according to GCP (Good Clinical Practice) guide lines will be assessed. In the proper formulations and at the appropriate sizes, liposomes deliver drugs to the skin on the basis of the similarity of the bilayer structure of the lipid vesicles to that of the natural membrane and target the macrophages within the dermis. Inclusion criteria are parasitologically proven cases of CL based on positive smear and/or culture and age 12-60 years and exclusion criteria are pregnant or lactating women and duration of lesion more than 6 months. A total of 120 patients will be recruited and randomly assigned in 2 groups. The patient will follow upto 6 months after beginning of the treatment. The primary clinical efficacy parameter will be the complete re-epithelization of all lesions with disappearance of induration (with or without scar).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904241475N5**

Registration date: **2015-09-21, 1394/06/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-09-21, 1394/06/30

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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+98 21 8897 0657

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Recruitment status

Recruitment complete

Funding source

The Eastern Mediterranean Regional Office (EMRO) of the World Health Organization (WHO)

Expected recruitment start date

2011-04-04, 1390/01/15

Expected recruitment end date

2011-10-07, 1390/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double blind, randomized clinical trial on efficacy of combination of meglumine antimoniate (Glucantime) and topical nano-liposomal paromomycin for the treatment of anthroponotic cutaneous leishmaniasis (ACL) caused by Leishmania tropica

Public title
Double blind, randomized clinical trial on efficacy of combination of Glucantime and topical paromomycin for the treatment of cutaneous leishmaniasis caused by Leishmania tropica

Purpose
Treatment

Inclusion/Exclusion criteria
I) Inclusion criteria:a) Parasitologically proven cases* of CL based on positive smear and/or culture; b) Otherwise healthy subjects on the basis of medical history, physical examination and results of blood test (if seemed necessary by the physician); c) Age 12-60 years; d) Willing to participate in the study and sign the informed consent (by the patient or his/her parent/guardian in case of younger than 18 years). * Direct smear, culture and PCR will be done on every sample to identify the causative agent. II) Exclusion criteria: a) Pregnant or lactating women; b) Duration of lesion more than 6 months; c) Number of lesions more than 4; d) Ulcer size greater than 3 cm in their largest diameter; e) History of full course of standard treatment (antimonials); f) History of allergy to Glucantime; g) Serious systemic illnesses (as judged by the physician); h) Participation in any drug trials in the last 60 days.

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
National Ethical Committee on Biomedical Research

Street address
Ministry of Health

City
Tehran

Postal code

Approval date
2010-07-31, 1389/05/09

Ethics committee reference number
1K89P/28

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 re-epithelization of all lesions with disappearance of induration

Timepoint
weekly

Method of measurement
Digital pictures

Secondary outcomes

1

Description
Reduction in the size of ulcer and induration.

Timepoint
weekly

Method of measurement
Digital pictures

Intervention groups

1

Description
Control:Glucantime (60 mg/kg/day) intramuscularly for 21days together with topical placebo twice daily for 28 days

Category
Placebo

2

Description
Intervention:Glucantime (60 mg/kg/day) intramuscularly

for 21days together with topical Lip-PM twice a day for 28 days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Center for Research and Training in Skin Diseases and Leprosy

Full name of responsible person
Ali Khamesipour

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

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The Eastern Mediterranean Regional Office (EMRO) of the World Health Organization (WHO)

Full name of responsible person
Ali Khamesipour

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

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
The Eastern Mediterranean Regional Office (EMRO) of the World Health Organization (WHO)

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

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Position
Associate Prof.

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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