

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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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		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
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		
<u>1</u>		
Ethics committee		
	Health conditions studied	
	<u>1</u>	
	Description of health condition studied	Protozoal diseases
	ICD-10 code	B55.1
	ICD-10 code description	Cutaneous leishmaniasis
	Primary outcomes	
	<u>1</u>	
	Description	complete re-epithelization of all lesions with disappearance of induration
	Timepoint	weekly
	Method of measurement	Digital pictures
	Secondary outcomes	
	<u>1</u>	
	Description	Reduction in the size of ulcer and induration.
	Timepoint	weekly
	Method of measurement	Digital pictures
	Intervention groups	
	<u>1</u>	
	Description	Control:Glucantime (60 mg/kg/day) intramuscularly for 21days together with topical placebo twice daily for 28 days
	Category	Placebo
	<u>2</u>	
	Description	Intervention:Glucantime (60 mg/kg/day) intramuscularly

for 21 days 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

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Full name of responsible person

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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