Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Double blind, randomized phase 3 efficacy trial of topical nano-liposomal paromomycin in the treatment of cutaneous leishmaniasis caused by L. major

Protocol summary

Summary

The aim of this clinical trial is to assess the efficacy of topical nano-liposomal 10 % paromomycin (Lip-PM) in the treatment of cutaneous leishmaniasis (CL) caused by L. major compared with placebo. Inclusion criteria are parasitologically proven cases of CL based on positive smear and/or culture, age 12-60 years, duration of lesion less than 3 months, number of lesions at most 5, lesion size not more than 30 mm in one direction, be volunteer to participate and sign informed consent, exclusion criteria are pregnant or lactating women and duration of lesion more than 3 months, participation in any other trial in last 6 months. A total of 144 ZCL patients will be recruited and double blind randomly assigned in 2 arms, 72 patients in each arm. The patients will be double blind randomly receiving either topical Lip-PM or placebo twice daily for 4 weeks (28 days), the study will be completed according to GCP (Good Clinical Practice) guide lines. The patients will be visited at week 4, 8 and at 3 and 6 months after initiation of treatment. At each visit the lesions' characteristics such as size of induration, ulcer and scar will be recorded. The data will be compared between the patients who received the treatment (Lip-PM) wand the group who received placebo. The follow up of the patients is for 6 months after beginning of the treatment. The primary clinical efficacy parameter is complete re-epithelization of all lesions with disappearance of induration (with or without scar).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108301475N6**
Registration date: **2011-10-05, 1390/07/13**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2011-10-05, 1390/07/13

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

Zoonoses control Center for diseases control Ministry of Health and..; Center for Research & Training in Skin Diseases & Leprosy, Tehran University of Medical Sciences; Nanotechnology Research Center Mashhad University of Medical Sciences

Expected recruitment start date

2011-09-01, 1390/06/10

Expected recruitment end date

2012-03-01, 1390/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double blind, randomized phase 3 efficacy trial of topical

nano-liposomal paromomycin in the treatment of cutaneous leishmaniasis caused by L. major

Public title
Double blind, randomized phase 3 efficacy trial of topical nano-liposomal paromomycin in the treatment of cutaneous leishmaniasis caused by L. major
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:Age 12-60 years; Cutaneous leishmaniasis (CL) lesion induced by L. major; Parasitological proven cases of CL by direct smear, culture or PCR; Healthy individual otherwise of CL; onset less than 3 months; number of lesion 5 at most; ulcer size not more than 30 mm in one size; willing to participate and sign informed consent. Exclusion criteria: pregnant or lactating women; duration of lesion more than 3 months; serious illness such as heart kidney or liver diseases based on physical exam and laboratory tests; CL lesion resistant to treatment or recidivans form of lesion; number of lesions more than 5; ulcer size more than 30 mm in one direction participation in any other clinical trial in last 6 months.
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: **144**
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
University Ethical Committee, Center for Research and Training in Skin Diseases and Leprosy, Tehran
Street address
415 Taleghani Avenue
City
Tehran
Postal code
1416613675
Approval date
2011-05-14, 1390/02/24
Ethics committee reference number
J/423/201

Health conditions studied

1

Description of health condition studied
Cutaneous leishmaniasis otherwise Healthy
ICD-10 code
B55.1
ICD-10 code description
minor skin disease

Primary outcomes

1

Description
Complete cure
Timepoint
at weeks 4 and 8 and at months 3 and 6
Method of measurement
Measurement of reepithelization

Secondary outcomes

1

Description
Partial cure
Timepoint
at weeks 4 and 8 and at months 3 and 6
Method of measurement
Measurement of reepithelization

Intervention groups

1

Description
Treatment with topical Nano liposomal form of 10% paromomycin, twice a day for 28 days
Category
Treatment - Drugs

2

Description
Placebo topically is used twice a day for 28 days
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Health Center, Isfahan University of Medical Sciences

Full name of responsible person
Dr Fariba Farid

Street address
Isfahan University of Medical Sciences, Vice Chancellor for Health

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Center for Research & Training in Skin Diseases & Leprosy Tehran University of Medical Sciences; Dis

Full name of responsible person
Dr Alireza Firooz, Dr Gooya or Shirzadi, Dr Jaafari

Street address
415 Taleghani Avenue, Hafez Avanue, BooAli Sq

City
Tehran, Tehran, Mashad

Grant name

Grant code / Reference number

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

Title of funding source
Center for Research & Training in Skin Diseases & Leprosy Tehran University of Medical Sciences; Dis

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

Full name of responsible person
Dr Ali Khamesipour

Position
Prof/PhD

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