Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Randomized, double blind, clinical trial on efficacy of topical nano-liposomal amphotericin B for the treatment of anthroponotic cutaneous leishmaniasis (ACL) caused by Leishmania tropica (Phase 3)

Protocol summary

Summary

Treatment of Cutaneous Leishmaniasis (CL) according to WHO is depend on pentavalent antimonials as first-line treatment which requires multiple injections, painful, costly; as such not tolerated by most of the patients resulted in low compliance, justify to search for more effective and tolerable treatment for CL. In this study the efficacy of topical Nano liposomal form of Amphotericin B, twice a day for 28 days in combination with National standard treatment will be compared with National standard treatment for the treatment of CL caused by L. tropica. Inclusion criteria are parasitologically proven cases of CL based on positive smear and/or culture and PCR, age 12-60 years and exclusion criteria are pregnant or lactating women and duration of lesion more than 6 months. Each patient will be clinically checked and samples from the lesion will be taken to test for direct smear, culture and PCR. If the patient agrees to sign an informed consent will be included in the study. All the patients will be receiving Glucantime as National CL treatment, and double blind randomly will be treated with topical Nano liposomal Amphotericin B or placebo, twice a day for 28 days. The patients will be visited on day 1, 7, 14, 21, 28, 35, 42, 56, 90 and 180. The lesion(s) characteristics and size will be recorded at each visit and the data will double enter the computer and will be analyzed to compare the two group treatments. The clinical trial will carried out according to GCP (Good Clinical Practice) guide lines.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504211475N7**
Registration date: **2015-11-22, 1394/09/01**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-11-22, 1394/09/01

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)

Phone

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Recruitment status

Recruitment complete

Funding source

WHO

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-04-19, 1395/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized, double blind, clinical trial on efficacy of topical nano-liposomal amphotericin B for the treatment of anthroponotic cutaneous leishmaniasis (ACL) caused by Leishmania tropica (Phase 3)

Public title
Clinical trial of efficacy of combination of topical liposomal Amphotericin B and meglumine antimoniate (Glucantime) the treatment of anthroponotic cutaneous leishmaniasis (ACL) caused by Leishmania tropica (Phase 3)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Inclusion criteria: Male or female aged between 12 to 60 years. Parasitologically proven CL due to L. tropica. In general good health based on history and physical examination. Number of lesion at most 5. Lesion size less than 3 cm. Signed informed consent voluntarily and knowingly**. ** Guardian’s signature for volunteer less than 18 years old. Exclusion criteria: Pregnancy lactating women Use of other types of treatment for CL. Involvement in any other drug or vaccine trial during the study period. Known heart, kidney, liver diseases based on history and physical exam.
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
TUMS, Ethical Committee
Street address
Keshavarz Blv
City
Tehran
Postal code
Approval date
2014-10-14, 1393/07/22
Ethics committee reference number
130/1676/93/ص

Health conditions studied

1

Description of health condition studied
Cutaneous leishmaniasis
ICD-10 code
B55.1
ICD-10 code description
Cutaneous leishmaniasis

Primary outcomes

1

Description
Complete cure
Timepoint
at week 4, 8, and days 90 and 180
Method of measurement
measurement of lesion status

Secondary outcomes

1

Description
Lesion(s) partial cure
Timepoint
at week 4, 8 and days 90 and 180
Method of measurement
measurement of lesion size

Intervention groups

1

Description
Nano Liposome Amphotricin B
Category
Treatment - Drugs

2

Description
Treatment with topical nano liposomal form of Amphotericin B twice a day for 28 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorasan Razavi Province Health Center
Full name of responsible person
Dr Hossein Ghorchi/Dr Ali Khamesipour

Street address
Vila Street, Vila 13
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
MoH, EMRO/WHO
Full name of responsible person
Ahmed Mohamed Amin, Ali Khamesipour
Street address
Nasr City, Cairo 11371, Egypt, Tehran, Iran
City
Cairo
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
MoH, EMRO/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
Mashhad University of Medical Sciences
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Dr Mohammad Hossein Ghoorchi
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Person responsible for scientific inquiries

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Postal code
Phone
00
Fax
Email
Web page address

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