Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

Summary

Amphotericin B is an antibiotic naturally produced by Streptomyces nodosus. Amphotericin B is insoluble in water and is used as sodium deoxycholate as an emulsifying agent to maintain the suspension in Fugizone which due to side effects has a limited use. Amphotericin B is used against fungal infection and visceral leishmaniasis (VL). In line of decreasing side effects, various formulation of Amphotericin B were produced and the most effective formulation is liposomal form of Amphotericin B (AmBisome™) with a limited side effect. Ambisome injection IV, is the treatment of choice for VL in Indian continent but showed limited efficacy in the treatment of cutaneous leishmaniasis (CL). In previous studies completed by the same group, several topical formulations of liposomal form of Amphotericin B were produced. With financial support of DNDi, Geneva, Switzerland, liposomal formulation form of Amphotericin B was produced under GMP condition, in vitro including size and morphology, percent of encapsulation, stability, the rate of skin penetration, drug analysis were performed. The effect of formulation against L. tropica in vitro was assessed and Draize test was done on rabbit's ocular and skin. In the present study the efficacy of topical formulation of amphotericin B will be checked on CL caused by L. major.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510161475N10**
Registration date: **2016-02-29, 1394/12/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-29, 1394/12/10

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

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Phone

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Recruitment status

Recruitment complete

Funding source

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

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

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

Public title

Efficacy of topical nano-liposomal Amphotericin B in the

treatment of cutaneous leishmaniasis caused by L. major

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Males & females 12-60 years of age; parasitologically proven CL caused by L. major (identification is done by using PCR); Otherwise healthy subjects on the basis of medical history, physical examination and results of blood test if requested by the physician; Ability to understand the principles of the trial; Signed informed consent voluntarily and knowingly.

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: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Cohort Study

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

2015-09-21, 1394/06/30

Ethics committee reference number

IR.TUMS.REC 1304-804

2

Ethics committee

Name of ethics committee

TUMS Ethical Committee

Street address

Keshavarz Blv

City

Tehran

Postal code

Approval date

2015-09-21, 1394/06/30

Ethics committee reference number

IR.TUMS.REC 1304-804

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 reepithelization of the lesions

Timepoint

Monthly

Method of measurement

Digital photos

Secondary outcomes

1

Description

Decrease size of the lesions

Timepoint

Monthly

Method of measurement

Digital photos

Intervention groups

1

Description

topical Nano Liposomal form of Amphotericin B twice a day for 28 days

Category

Treatment - Drugs

2

Description

Placebo ointment without liposomes or Amphotericin B

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Pategah 8 Shekari
Full name of responsible person
Dr Meshkforoush
Street address
City
Esfahan

2

Recruitment center
Name of recruitment center
Payegah 8 Shekari
Full name of responsible person
Dr Meshkforoush
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran Nanotechnology, Inititave concil
Full name of responsible person
Dr Saeed Sarkar
Street address
Sattar Khan Str. Habibollahi Ave, Motovalian No 9
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran Nanotechnology, Inititave concil
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
CRTSDL, TUMS
Full name of responsible person
Prof Firooz
Street address
No 415, Taleghani Ave
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
CRTSDL, TUMS
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
Payegah 8th Shekari
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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