Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Safety Evaluation of Topical Application of Nano-Liposomal Form of Amphotericin B (Sinaampholeish) in comparison with placebo on Healthy Volunteers; Phase I Clinical Trial.

Protocol summary

Study aim
To evaluate the safety of SinaAmpholeish in a double-blind, randomized, phase 1 clinical trial in healthy human volunteers.

Design
A randomized controlled trial, parallel, double-blind with the sample size of 27 volunteers (left and right volar side of their forearm).

Settings and conduct
54 forearms of 27 healthy volunteers who are blinded to intervention groups are randomly assigned to the active group and receive topical Nano-liposomal amphotericin-B 0.4% on one side and receive placebo on the other side of their forearms.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Healthy volunteer aged between 18-65 who are willing to participate in the study and signing the informed consent. Exclusion Criteria: The history of any diseases or illness, mental illness, participating in another trial concurrently

Intervention groups
Intervention group includes left or right sides of the volar side of forearms which topical Nano-liposomal amphotericin-B 0.4% (15-g tubes), Razak Laboratories Company was applied. Control group include the opposite side of participants forearm which only receive the placebo (vehicle of active drug).

Main outcome variables
Erythema, Pruritus, and other possible adverse reaction (by clinical exam or participants history)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20081130001475N12**
Registration date: **2019-02-21, 1397/12/02**
Registration timing: **retrospective**

Last update: **2019-02-21, 1397/12/02**
Update count: **0**

Registration date
2019-02-21, 1397/12/02

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

Expected recruitment start date
2012-06-13, 1391/03/24

Expected recruitment end date
2012-07-13, 1391/04/23

Actual recruitment start date
2012-07-13, 1391/04/23

Actual recruitment end date
2012-07-13, 1391/04/23

Trial completion date
2012-07-13, 1391/04/23

Scientific title
Safety Evaluation of Topical Application of Nano-Liposomal Form of Amphotericin B (Sinaampholeish) in

comparison with placebo on Healthy Volunteers; Phase I Clinical Trial.

Public title
"Safety Evaluation of Topical Application of Nano-Liposomal Amphotericin B (Sinaampholeish)"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy volunteer aged between 18-65 willingness to participate in the study and signing the informed consent form
Exclusion criteria:
Any disease or illness according to subject history
Mentally ill based on physician diagnosis participating in other concurrent trial
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
1
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **27**
More than 1 sample in each individual
Number of samples in each individual: **2**
The volar side of left or right forearm in each participant
Actual sample size reached: **27**
More than 1 sample in each individual
Actual sample size in each individual: **2**
The volar side of left or right forearm in each participant
Randomization (investigator's opinion)
Randomized
Randomization description
The master sheet of randomization was generated using online software before study conduct (Simple randomization method). Trial labels were put on the drugs. The Nano-liposomal formulation of amphotericin-B and its vehicle (as placebo) were prepared in identical tubes.
Blinding (investigator's opinion)
Double blinded
Blinding description
Regarding the similar appearance of active drug and placebo, neither the volunteers nor the investigators were aware of the type of medication applied on each side.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Center for Research & Training in Skin Diseases & Leprosy, Tehran University of
Street address
No. 415, Taleghani St., Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
14166-13675
Approval date
2012-06-13, 1391/03/24
Ethics committee reference number
92-3450

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
Erythema
Timepoint
Daily evaluation after the 1st day of intervention to 7th day.
Method of measurement
clinical exam

2

Description
Pruritus
Timepoint
Daily evaluation after the 1st day of intervention to 7th day.
Method of measurement
clinical Exam

Secondary outcomes

1

Description
Any reported adverse events
Timepoint

Daily evaluation after the 1st day of intervention to 7th day.

Method of measurement

Participants history

Intervention groups

1

Description

Intervention group: Topical Nano-liposomal formulation of 0.4% Amphotericin B was applied on the left or right volar side of forearm twice a day for one week

Category

Treatment - Drugs

2

Description

Control group: ،Topical placebo (vehicle of active drug) was applied on the left or right volar side of forearm twice a day for one week

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

Alireza Firooz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Neglected Diseases Initiative

Full name of responsible person

Neglected Diseases Initiative (DNDi)

Street address

15 Chemin Louis-Dunant 1202 Geneva Switzerland

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Web page address

https://www.dndi.org/

Grant name

Safety Evaluation of Topical Application of Nano-Liposomal Form of Amphotericin B (Sinaampholeish) on Healthy Volunteers; Phase I Clinical Trial

Grant code / Reference number

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

Yes

Title of funding source

Neglected Diseases Initiative

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

UN agencies and international organizations

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooze

Position

Profosser

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available