Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of Efficacy and Safety of Topical Nano-liposomal Amphotericin B 0.4% for Treatment of Onychomycosis: An Interventional Clinical Pilot Study

Protocol summary

Study aim
Evaluation of efficacy and safety of topical nano-liposomal amphotericin B 0.4% to treatment of onychomycosis

Design
Interventional Clinical Pilot Study , Single group , Sample size of 15 persons

Settings and conduct
Patients should use topical 0.4% nanoliposomal amphotericin B twice a day on the whole surface of affected nails and 5mm of the contiguous skin. the treatment duration is 12 weeks for fingernails and 24 weeks for toenails. after the first visit, 3 follow-up visits at week 12, 24 and 36 will take place. the endpoint of the study will be at week 24 or 36.

Participants/Inclusion and exclusion criteria
Inclusion: 18 to 60 y/o, good general health, effective nail growth, compliance, confirmed diagnosis of onychomycosis Exclusion: Oral/ IV antifungal therapy in the past 12w, or topical in the past 4w, immunosuppression, Uncontrolled DM, nail surgery, concomitant nail disease, pregnancy

Intervention groups
Intervention: topical nano-liposomal amphotericin B 0.4% twice daily for 12 and 36 weeks on target finger and toe nails respectively.

Main outcome variables
states of partial clinical response (PCR), effective clinical response (ECR), complete cure (CC), mycological cure (MC)

General information

Reason for update

Acronym
amb

IRCT registration information
IRCT registration number: **IRCT20150101020514N18**
Registration date: **2023-01-05, 1401/10/15**
Registration timing: **retrospective**

Last update: **2023-01-05, 1401/10/15**
Update count: **0**

Registration date
2023-01-05, 1401/10/15

Registrant information

Name
Alireza Firooz

Name of organization / entity
Tehran University of Medical Science

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-26, 1400/04/05

Expected recruitment end date
2021-08-31, 1400/06/09

Actual recruitment start date
2021-06-26, 1400/04/05

Actual recruitment end date
2021-07-27, 1400/05/05

Trial completion date
2022-12-19, 1401/09/28

Scientific title
Evaluation of Efficacy and Safety of Topical Nano-liposomal Amphotericin B 0.4% for Treatment of

Onychomycosis: An Interventional Clinical Pilot Study

Public title

Efficacy of topical Nano-liposomal Amphotericin B 0.4% for Treatment of Onychomycosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female subjects of any race, 18 to 60 years of age (inclusive). Verbal and written informed consent/assent obtained from the subject. Good general health, as assessed by the investigator, based on the subject's medical history, physical examination, and safety laboratory tests. Target nails for all subjects, must have had evidence of nail growth, per subject's report that monthly clipping is needed. Subjects are willing to comply with study instructions and return to the vising clinic for all required appointments each 12 weeks for at least 3 visits. confirmed diagnosis of onychomycosis via KOH direct smear and positive culture

Exclusion criteria:

Male or female who have received oral/ IV antifungal therapy within the past 12 weeks prior to screening. the male or female individual were used topical antifungal during the previous 4 weeks before screening Patients who had a history of immunosuppression /or clinical evidence indicating possible immunosuppression. Uncontrolled diabetics. Patients that have performed a surgical intervention for nail dystrophy in the past. Any illness or condition that could have caused nail anomalies or adversely affected the assessment. Or, presence of any nail infection other than onychomycosis or in addition to onychomycosis. Patients who had received immunosuppressive therapy in the past 3 months prior to screening visit or who had the need for it. Females who are pregnant, nursing a child, or planning a pregnancy during the study duration.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **15**

Actual sample size reached: **15**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Research Ethics Committee of Tehran University

Street address

Tehran university of medical science

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-06-18, 1398/03/28

Ethics committee reference number

IR.TUMS.VCR.REC.1398.304

Health conditions studied

1

Description of health condition studied

Fungal nail Infection

ICD-10 code

L62.8

ICD-10 code description

Nail disorders in other diseases classified elsewhere

Primary outcomes

1

Description

state of clinical response, including: 1-partial clinical improvement which means decrease in the nail surface involvement to 10 -50% nail bed surface , or complete cure which means decrease in the nail surface involvement to <10% nail bed surface.

Timepoint

Base (first visit) / week 12/ week 24 / week 36

Method of measurement

Physical examination, direct examination and culture for fungal elements

2

Description

Mycological cure

Timepoint

Base (first visit) / week 12/ week 24 / week 36

Method of measurement

Physical examination, direct examination and culture for fungal elements

Secondary outcomes

empty

Intervention groups

1

Description
0.4% nano-liposomal amphotericin B gel is prescribed for the patients after they are educated on how to properly use the medication. Patients are asked to apply the gel topically twice daily on the entire surface of the affected nails and on a 6mm margin around the cuticle. The treatment must be done minimum 12 weeks for patient with finger nail onychomycosis and 24 weeks for those with toe nail onychomycosis.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Center for Research and Training in Skin Disease and Leprosy

Full name of responsible person
Dr. Mahsa Fattahi

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Taleghani Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Center For Research and Training in Skin Disease and Leprosy

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Alireza Firooz

Position
Directory of recerach center for skin disese and leprosy

Latest degree
Subspecialist

Other areas of specialty/work
Dermatology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Only in published article
When the data will become available and for how long
After publication of article
To whom data/document is available
Clinicians, pharmacologist, medical mycologist
Under which criteria data/document could be used

From where data/document is obtainable
Center for Research and Training in Skin Disease and Leprosy
What processes are involved for a request to access data/document
After publication of article
Comments