

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 8190

Email address

firozali@tums.ac.ir

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

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 visting 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

Street address

Taleghani Ave.

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Fax

+98 21 8896 3804

Email

dr.mahsafattahi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Center For Research and Training in Skin Disease and Leprosy

Full name of responsible person

Dr. Alireza Firooz

Street address

Taleghani ave

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Fax

+98 21 8896 3804

Email

alifiruz@yahoo.com

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

Street address

Taleghani ave

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Fax

+98 21 8896 3804

Email

alifiruz@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooz

Position

Center for research and training in skin disease and leprosy

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

Street address

Taleghani ave

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Email

firozali@sina.tums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr.Mahsa Fattahi

Position

Assistant proffessor of medical mycology

Latest degree

Ph.D.

Other areas of specialty/work

Mycology

Street address

Taleghani ave

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Email

dr.mahsafattahi@gmail.com

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