

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 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

#### 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 diseas and leprosy

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Dermatology

#### Street address

Taleghani ave

#### City

Tehran

#### Province

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#### Postal code

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#### Phone

+98 21 8897 2220

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#### 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**

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**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**

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**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****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 professor of medical mycology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Mycology

**Street address**

Taleghani ave

**City**

Tehran

**Province**