Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Determining the efficacy of topical nanoliposomal amphotericin B in individuals with treatment-resistant dermatophytosis.

Protocol summary

Study aim
Evaluating the efficacy of nanoliposomal amphotericin B in patients with treatment-resistant dermatophytosis

Design
A controlled, parallel-group, single-blind, randomized, phase 1 clinical trial was conducted on 75 patients with treatment-resistant dermatophytosis. Randomization was performed using Random Allocation software.

Settings and conduct
"The present study is a single-blind randomized clinical trial conducted on 75 patients with treatment-resistant dermatophytosis, who will be recruited from Tuba Baghban Specialty Clinic and cosmetic dermatology clinics in Sari, Iran, between 2024-2025.

Participants/Inclusion and exclusion criteria
"Inclusion Criteria: Patients with treatment-resistant dermatophytosis Exclusion Criteria: Children, infants, pregnant women, and individuals who have received antifungal therapy within the past week."

Intervention groups
Group 1: Patients with treatment-resistant Dermatophytosis, who will receive nanoliposomal amphotericin B. Group 2: Patients with treatment-resistant Dermatophytosis, who will receive both nanoliposomal amphotericin B and itraconazole. Group 3: Patients with treatment-resistant dermatophytosis, who will receive itraconazole (200 mg/day for 4 weeks) as the control group.

Main outcome variables
Complete recovery of clinical symptoms Negative mycological criteria: negative result in direct examination or culture

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240711062393N2**
Registration date: **2025-06-07, 1404/03/17**
Registration timing: **prospective**

Last update: **2025-06-07, 1404/03/17**
Update count: **0**

Registration date
2025-06-07, 1404/03/17

Registrant information
Name
Mahdi Abastabar
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-07-23, 1404/05/01
Expected recruitment end date
2026-01-21, 1404/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Determining the efficacy of topical nanoliposomal amphotericin B in individuals with treatment-resistant dermatophytosis.

Public title
Evaluation of the effect of nanoliposomal amphotericin B

in the treatment of patients with resistant dermatophytosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with treatment-resistant Dermatophytosis

Exclusion criteria:

Neonates and children range from 0 to 19 years

Pregnant mothers

Age

From **20 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization For randomization, the block randomization method will be used. Participants are divided into small blocks (e.g., 4 or 6 individuals per block), with an equal number assigned to each group within each block. In this study, the unit of randomization is individual, as each patient is independently assigned to one of the groups. The Random Allocation software is used to generate the random sequence. Implementation mechanism: The block size and number of blocks are determined randomly and unpredictably by the software. After generating the sequence, patients are assigned to different groups based on the produced numbers. Single-Blinding Participants are unaware of which group they are in (nanosomal amphotericin B + itraconazole vs. nanosomal amphotericin B alone). Researchers and assessors are aware of the treatment type. Allocation Concealment To prevent selection bias, it must be ensured that researchers are unaware of future patient assignments before enrollment. Methods include: Sealed opaque envelopes: Random numbers are placed in sealed, non-transparent envelopes. Electronic system: The Random Allocation software determines the treatment group only after patient registration. In this study: The software is used, so allocation remains concealed until the moment of patient enrollment.

Blinding (investigator's opinion)

Single blinded

Blinding description

Simultaneously, the participants receive information regarding conducting a research study and complete the consent form; however, the type of gel (simple or nano form) will remain concealed from her.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Moalem square

City

Sari

Province

Mazandaran

Postal code

4817844718

Approval date

2025-04-07, 1404/01/18

Ethics committee reference number

IR.MAZUMS.REC.1404.020

Health conditions studied

1

Description of health condition studied

Dermatophytosis is an inflammatory skin infection caused by dermatophyte fungi including Trichophyton, Microsporum, Epidermophyton, Lophophyton, Nannizzia, Parathion, and Arthroderma.

ICD-10 code

B35

ICD-10 code description

Dermatophytosis

Primary outcomes

1

Description

Percentage of Individuals with treatment-resistant dermatophytosis

Timepoint

Patients are evaluated at the beginning of the study

Method of measurement

Assessing lesion size, itch, and inflammation based on observation.

2

Description

Complete clinical response

Timepoint

Patients are evaluated after 2 and 4 weeks of treatment

Method of measurement

Assessing improvement of lesion size, itch, and inflammation based on the questionnaire scoring

3

Description
No response to treatment
Timepoint
Patients are evaluated after 2 and 4 weeks of treatment
Method of measurement
Assessing improvement of lesion size, itch, and inflammation based on the questionnaire scoring

4

Description
Independent variable-Nano-Liposomal Amphotercin b drug
Timepoint
Patients are evaluated after 2 and 4 weeks of treatment
Method of measurement
Patient grouping (drug-receiving group vs. control)

5

Description
Dependent variable-effectiveness
Timepoint
Patients are evaluated after 2 and 4 weeks of treatment
Method of measurement
Clinical outcomes

Secondary outcomes

empty

Intervention groups

1

Description
Group 1: Patients with treatment-resistant dermatophytosis (non-onychomycosis) who will receive nanoliposomal amphotericin B. Sina Ampholish 0.4% ointment is used twice a day for 4 weeks.
Category
Treatment - Drugs

2

Description
Group 2: Patients with treatment-resistant dermatophytosis, non-onychomycosis, who will receive nanoliposomal amphotericin B and itraconazole. Sina Ampholish 0.4% ointment is used twice a day, and itraconazole 200 mg tablet is taken once a day for 4 weeks
Category
Treatment - Drugs

3

Description
Control group: Patients with treatment-resistant dermatophytosis (non-onychomycosis) who will receive itraconazole (200 mg per day for 4 weeks) will serve as the control group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baghban Specialized Clinic (Tuba) & Baran Clinic, Sari, Iran
Full name of responsible person
Ghasem Rahmatpour Rokni
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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
Mazandaran University of Medical Sciences
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
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Position
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Contributors' data in the study is shareable once it is unidentifiable.
When the data will become available and for how long
The access period begins six months after the results are published.
To whom data/document is available
Researchers who are working at universities
Under which criteria data/document could be used
This information is only for comparison with similar research
From where data/document is obtainable
The information provided is only intended for comparison with similar research
What processes are involved for a request to access data/document
Project data sets will be housed on the website and/or

the file transfer protocol site created for the study, and all data sets will be password-protected. Project Principal Investigators will have direct access to their own site’s data sets and access to other sites' data by request. To ensure confidentiality, data dispersed to project team members will be blinded to any identifying participant information

Comments