Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Efficacy Evaluation of Loaded Nanostructured Lipid Carriers (NLC) with Luliconazole in Treatment-Resistant Dermatophytosis

Protocol summary

Study aim
Determining the effect of nanostructured lipid carriers (NLCs) loaded with luliconazole on patients with treatment-resistant dermatophytosis.

Design
The first group: patients with treatment-resistant dermatophytosis, and non-onychomycosis, who will receive itraconazole, will be the control group. The second group: patients with treatment-resistant dermatophytosis, not onychomycosis, who will receive NLC gel drug loaded with luliconazole. The third group: patients with treatment-resistant dermatophytosis, non-onychomycosis, who will receive NLC gel drug loaded with loliconazole and itraconazole.

Settings and conduct
The current research is a clinical trial study that will be conducted on 75 patients with treatment-resistant dermatophytosis who were referred to the Baghban (Tubi) specialized clinic and skin and beauty clinics in Sari City during the years 1403-1404. The study is single-blind, so patients will not know the type of medicine they receive.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with treatment-resistant dermatophytosis Exclusion criteria: children, neonates, and individuals who took the drugs in the last week.

Intervention groups
After diagnosis by a specialist, patients with dermatophytosis are identified through clinical and laboratory methods, including history of treatment. The study includes common antifungals like terbinafine. After confirming terbinafine-resistant cases, patients will be grouped according to the protocol and prescribed the appropriate medication. Patients will receive medicine for two weeks.

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: **IRCT20240711062393N1**
Registration date: **2024-07-25, 1403/05/04**
Registration timing: **prospective**

Last update: **2024-07-25, 1403/05/04**
Update count: **0**

Registration date
2024-07-25, 1403/05/04

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
2024-08-10, 1403/05/20
Expected recruitment end date
2024-11-10, 1403/08/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Efficacy Evaluation of Loaded Nanostructured Lipid Carriers (NLC) with Luliconazole in Treatment-Resistant Dermatophytosis

Public title
Efficacy Evaluation of Nano-Luliconazole in Patients with Treatment-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
Gender
Both

Phase
1
Groups that have been masked

- Participant

Sample size
Target sample size: **75**
More than 1 sample in each individual
Number of samples in each individual: **75**
The first group, patients with treatment-resistant dermatophytosis and non-onychomycosis, who will receive itraconazole, will be the control group. The second group consists of patients with treatment-resistant dermatophytosis, without onychomycosis, who will be receiving the NLC gel drug loaded with luliconazole. The third group consists of patients with treatment-resistant dermatophytosis, and non-onychomycosis who will receive NLC gel drug loaded with loliconazole and itraconazole.
Randomization (investigator's opinion)
Randomized
Randomization description
randomization The block method will be used for randomization. This will be performed using Random allocation software. To ensure unpredictability, the software will calculates block number and size. Based on numbers produced by the software, samples are assigned to groups.
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 luliconazole 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
2024-05-14, 1403/02/25
Ethics committee reference number
IR.MAZUMS.REC.1403.048

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
individuals with treatment-resistant dermatophytosis
Timepoint
Patients are evaluated after 2 and 4 weeks of treatment.
Method of measurement
Assessing improvement, lesion size, itch, and inflammation based on the questionnaire's scoring.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group includes patients resistant to dermatophytosis other than onychomycosis

who take NLC gel loaded with luliconazole.

Category

Treatment - Drugs

2

Description

Intervention group: The second intervention group: patients resistant to dermatophytosis other than onychomycosis also receive itraconazole along with luliconazole.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

کلینیک تخصصی باغبان (طوبی) و کلینیک باران شهرستان ساری

Full name of responsible person

Ghasem Rahmatpour Rokni

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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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

Full name of responsible person

Mahdi Abastabar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Mycology

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Person responsible for scientific inquiries

Contact

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Other areas of specialty/work

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Other areas of specialty/work

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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 Web site 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 will have access to other sites' data by request. To ensure confidentiality, data dispersed to project team members will be blinded of any identifying participant information

Comments