

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Formulation design and evaluation of the effect of hyaluronic acid hydrogel loaded with terbinafine lipid nanostructures in the treatment of patients with onychomycosis

Protocol summary

Study aim

Designing the formulation and determining the effect of hyaluronic acid hydrogel loaded with terbinafine lipid nanostructures in the treatment of patients with onychomycosis.

Design

In this study, which is a double-blind clinical trial, 60 patients with the desired disease will enter the plan, who will be divided into 12 groups consist of 5 patients, according to gender and severity of the disease, and will receive hydrogel, placebo. All the patients should be the same in terms of the severity of the disease, the location of the lesion, and the age and gender range. After being referred by a doctor to a specialized mycology laboratory, the patient will be examined and if the microscopic observation and culture are positive, they will be included in the plan.

Settings and conduct

Tubi Clinic, Mazandaran, Medical Mycology Laboratory - After sampling and entering the plan, the patient will randomly receive the desired product and will be examined at intervals of 1, 2, and 4 weeks.

Participants/Inclusion and exclusion criteria

All patients with onychomycosis includes in the study and taking antifungal drugs and conscious withdrawing from the plan by patient or dermatologist will lead to exclude from the study.

Intervention groups

Intervention group: patients suffering from onychomycosis will use the desired product in a form of varnish in a package of 60 g, 2 times a day for one months as supplement along with the application of the drug of choice (Terbinafin tablet). Control group: patients with onychomycosis, the desired placebo is used in the form of varnish in a form of varnish in a package of 60 g, 2 times a day for one months.

Main outcome variables

Improvement of fungal lesions in terms of clinical and mycological criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210611051539N4**

Registration date: **2023-11-19, 1402/08/28**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-19, 1402/08/28**

Update count: **0**

Registration date

2023-11-19, 1402/08/28

Registrant information

Name

Maryam Moazeni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3325 7911

Email address

moazeni.maryam@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-06, 1402/08/15

Expected recruitment end date

2024-05-04, 1403/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Formulation design and evaluation of the effect of hyaluronic acid hydrogel loaded with terbinafine lipid nanostructures in the treatment of patients with onychomycosis

Public title
Investigating the effect of hyaluronic acid hydrogel loaded with terbinafine lipid nanostructures in the treatment of patients with onychomycosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients with onychomycosis
Exclusion criteria:
Taking antifungal drugs Conscious withdrawal of the patient Leaving the plan with the order of a dermatologist

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, terbinafine hydrogel and placebo will be prepared in identical packages and in order to observe random allocation, www.randomizer.org website is used by applying the codes received from the site, the drug and the placebo are separated and then placed inside a similar envelope and will give to the patients completely random. Therefore, the patients will not be informed about the nature of the drug and the type of group it belongs to. Also, both medicine and placebo are mixed together in a closed package and the doctor or expert randomly gives the medicine to the patient.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients participating in the study, as well as the researcher, who includes the PHD student who is responsible for completing his thesis, as well as the collaborating doctors who perform the intervention, are blinded in the study. The drug and placebo are all three with the same packaging in Special envelopes are placed and the associate doctors and students who perform the intervention are not aware of its contents. Only the drug code and the patient code will be written in the

questionnaire. But the project manager as an analyst is aware of the codes and their allocation to control and intervention groups. On the other hand, the participants are not aware of the content of the envelope, but they will be informed that their complementary medicine may be a placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mazandaran University of Medical Sciences ethics committee
Street address
Shayan 3 Bldg., Ghaem 12 St., Ghaem St., Moalem Sq.
City
Sari
Province
Mazandaran
Postal code
4817845423
Approval date
2023-01-24, 1401/11/04
Ethics committee reference number
IR.MAZUMS.REC.1401.511

Health conditions studied

1

Description of health condition studied
Onychomycosis
ICD-10 code
B35.1
ICD-10 code description
Tinea unguium

Primary outcomes

1

Description
improvement of fungal lesions in term of clinical and mycological criteria
Timepoint
before the start of the intervention and 1, 2 and 4 weeks after the start of the treatment
Method of measurement
Examination of clinical symptoms in terms of lesion healing by a doctor and examination in terms of direct

smear and fungal culture in the interval of 1, 2 and 4 weeks.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For patients with onychomycosis, terbinafine hydrogel and placebo in Mazandaran University of Medical Sciences in 100 gram tubes, 2 times a day for 1 months. This intervention is used as a medical supplement along with the drug of choice which is determined by a dermatologist.

Category

Treatment - Drugs

2

Description

Control group: Placebo is used for patients with onychomycosis in Mazandaran University of Medical Sciences in 60 gram tubes, 2 times a day for 1 months. This intervention is used as a medical supplement along with the drug of choice which is determined by a dermatologist.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tuba clinic

Full name of responsible person

Shima Parsay

Street address

Shayan 3 Bldg., Ghaem 12 St. Ghaem St.

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Mazandaran

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4817845423

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+98 912 294 2248

Email

moazeni.maryam@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Pedram Ebrahimnejad

Street address

Moalem Sq.

City

Sari

Province

Mazandaran

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4817845423

Phone

+98 11 5233 1197

Email

moazeni.maryam@gmail.com

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

Dr. Maryam Moazeni

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Mycology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All information related to the study protocol and the informed consent form will be shared after the publication of the results.

When the data will become available and for how long

After the publication of the desired article and results

To whom data/document is available

All researchers in the relevant field

Under which criteria data/document could be used

Citing sources

From where data/document is obtainable

The article resulting from the plan

What processes are involved for a request to access data/document

By sending an email or receiving an article

Comments

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Maryam Moazeni

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Mycology

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