Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

evaluation of antifungal supplement properties of zataria multiflora - loaded nanostructural lipid carriers in the treatment of onychomycosis caused by filamentous fungi

Protocol summary

Study aim

Determining the antifungal effect of supplementing lipid nanostructures loaded with Shirazi thyme on patients with onychomycosis caused by filamentous fungi.

Design

In this study, which is a double-blind clinical trial, 30 patients with the desired disease will be included in the plan, and out of 30 confirmed patients, 15 will be in the experimental group and 15 will be in the control group. All the patients 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

The location of the project will be in the specialized mycology laboratory of Mazandaran Medical Sciences, in Toubi Clinic, Mazandaran. After entering the sampling, the samples will be checked for fungal agents, and after recording the results, the patient will receive medicine or a placebo and will be evaluated at intervals of 2, 4, and 6 weeks.

Participants/Inclusion and exclusion criteria

Entry requirements: All patients with mild-moderate onychomycosis caused by filamentous fungi over 18 years of age who have not taken antifungal drugs a month before treatment. Exit conditions: 1- Taking antifungal drugs before and during the study 2- Children and infants 1-18 years old 3- Allergy to herbal products

Intervention groups

Intervention and control group: For patients with onychomycosis caused by filamentous fungi, 1% nano thyme gel made in Mazandaran University of Medical Sciences in 60 gram tubes is used twice a day for 1 month. It is used as an auxiliary drug along with the main drug (Itraconazole) which is determined by a specialist doctor. The control group will receive a placebo in addition to the main drug, the same as the intervention group

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: **IRCT20210611051539N3**
Registration date: **2023-03-05, 1401/12/14**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-05, 1401/12/14**
Update count: **0**

Registration date

2023-03-05, 1401/12/14

Registrant information

Name

Maryam Moazeni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3325 7911

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-19, 1401/11/30

Expected recruitment end date

2023-07-21, 1402/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation of antifungal supplement properties of zataria multiflora - loaded nanostructural lipid carriers in the treatment of onychomycosis caused by filamentous fungi

Public title

Evaluation of the effect of Nano zataria multiflra antifungal supplement on patients with onychomycosis with saprophytic agent

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All people over 18 years old with mild-moderate onychomycosis caused by filamentous fungi

Exclusion criteria:

Patients who have taken antifungal drugs during treatment

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In that study, nano thyme gel and placebo were prepared in completely similar packaging and drug tubes, and in order to observe random allocation, www.randomizer.org was used in such a way that by using the codes received from the site, the drug and The isolated placebo is then placed inside a similar envelope and presented to the patient in a completely random manner. Therefore, the patient will not be informed about the nature of the drug and the type of group it belongs to. Since the smell created by Shirazi thyme essential oil can cause deviations in the study, therefore, both the drug and the placebo are mixed together in a closed tube and the doctor or expert randomly gives the drug to the patient. Gives.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients participating in the study, as well as the researcher, including the master student who is responsible for their dissertation, as well as the physicians who perform the intervention, are among the people who are blinded in the study. The drug and placebo are both placed in similar envelopes. The fellow doctors and graduate students who are performing the intervention are not aware of its contents. Only the drug code and the patient code will be stated in the questionnaire. But the executor is aware of the code as an analyst and assigns it to control and intervention groups. Participants, on the other hand, are not aware of the contents of the envelope, but will be informed that their supplement may be a placebo.

Placebo

Used

Assignment

Parallel

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

Faculty of Medicine- Payambar azam university-18th Km of Farah Abad Road- Sari

City

Sari

Province

Mazandaran

Postal code

4817845423

Approval date

2023-01-24, 1401/11/04

Ethics committee reference number

IR.MAZUMS.REC.1401.496

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

improvment of fungal lesions in term of clinical and mycological criteria

Timepoint

before the intervention and 2,4 weeks after the treatment start

Method of measurement
Examining clinical symptoms such as inflammation, itching, scaling and examination in terms of direct smear and fungal culture in the interval of 2, 4 and 6 weeks.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: For patients with onychomycosis caused by filamentous fungi, 1% nano thyme gel made in Mazandaran University of Medical Sciences in 60 gram tubes is used twice a day for 1 month. Auxiliary medicine is taken along with the main medicine that is determined by a specialist doctor.
Category
Treatment - Drugs

2

Description
Control group: For patients with onychomycosis caused by filamentous fungi, a placebo gel made in Mazandaran University of Medical Sciences in 60 gram tubes is used twice a day for 1 month. It is consumed by a specialist doctor.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Toba Clinic
Full name of responsible person
Alireza Amini
Street address
Clinic toba , Khazar Blv, Khaxar Sq
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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
Dr. Maryam Moazeni
Position
Assistant professor
Latest degree
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Other areas of specialty/work
Mycology
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
The results of this study will be published in an article.

When the data will become available and for how long
Unknown

To whom data/document is available
Public

Under which criteria data/document could be used
To use the results of clinical trials and to register a patent

From where data/document is obtainable
Scientific journals and article search databases

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

Comments