

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of antifungal supplement properties of Zataria multiflora-loaded nanostructural lipid carriers on cutaneous candidiasis

Protocol summary

Study aim

Determination of antifungal supplement properties of Zataria multiflora-loaded nanostructural lipid carriers on cutaneous candidiasis. Determining the effectiveness of nano-thyme (in terms of mycological criteria) on the treatment of cutaneous candidiasis Identification of yeasts isolated from patients at the cheek level by PCR-RFLP technique

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 40 patients. www.randomizer.org was used to observe random allocation.

Settings and conduct

Forty patients referred by a physician in Sari whose cutaneous candidiasis has been confirmed by mycological criteria (direct testing and culture) are involved. Patients in each group should be the same in terms of disease severity, lesion location, age range and sex. Patients are evaluated after 2 and 4 weeks after the start of treatment in terms of recovery and the size of the lesions, itching and inflammation, according to the opinion of a specialist. the complete recovery is based on the negative criteria of mycology (direct and culture).

Participants/Inclusion and exclusion criteria

Inclusion criteria include all patients presenting with mild-moderate cutaneous candidiasis. It refers to patients who do not need treatment with systemic antifungals. Exclusion criteria are the use of antifungal drugs as well as children and infants in the age range of 0-10 years.

Intervention groups

In this study, 40 patients with different types of cutaneous candidiasis will be studied. Cutaneous candidiasis in suspected patients is diagnosed and approved by a specialist doctor and finally diagnosed in the laboratory with the mentioned methods and according to the inclusion criteria. Of the 40 patients confirmed, 20 will be a test sample and 20 will be a

control sample.

Main outcome variables

Treatment of cutaneous candidiasis lesions in terms of mycological criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210611051539N1**

Registration date: **2021-06-19, 1400/03/29**

Registration timing: **prospective**

Last update: **2021-06-19, 1400/03/29**

Update count: **0**

Registration date

2021-06-19, 1400/03/29

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

2021-07-06, 1400/04/15

Expected recruitment end date

2022-07-06, 1401/04/15

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 on cutaneous candidiasis

Public title

Effect of nano-Zataria multiflora supplement on cutaneous candidiasis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients presenting with mild-moderate cutaneous candidiasis and do not require treatment with systemic antifungals.

Exclusion criteria:

Taking antifungal drugs Children and infants in the age range of 0-10 years

AgeFrom **10 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

In order to observe random allocation, the site www.randomizer.org is used and using codes based on blocking people into 2 groups, even and odd codes are installed on the drug and placebo. Then, for each group of drugs and placebo, it is placed in a special envelope and the patient number and drug code are written on the envelope.

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

5th Floor, Shayan 3 Bldg., Ghaem 12 St, Ghaem St., Taleghani Blvd., Sari

City

Sari

Province

Mazandaran

Postal code

4817845423

Approval date

2021-06-08, 1400/03/18

Ethics committee reference number

IR.MAZUMS.REC.1400.230

Health conditions studied**1****Description of health condition studied**

Cutaneous candidiasis

ICD-10 code

B37.2

ICD-10 code description

Candidiasis of skin and nail

Primary outcomes**1****Description**

Improvement of fungal lesions in terms of mycological criteria

Timepoint

Before the intervention, 2 and 4 weeks after the intervention

Method of measurement

Evaluation of clinical symptoms such as erythema, inflammation and pruritus and evaluation of negative direct examination and mycology culture

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For patients with cutaneous candidiasis (except onychomycosis), 1% thyme nano-gel which is made by Mazandaran University of Medical Sciences in 60 g tubes, is applied twice a day for a month. This intervention is used as an adjunct to the main antifungal drug prescribed by dermatologist.

Category

Treatment - Drugs

2

Description

Control group: For patients with cutaneous candidiasis (except onychomycosis), placebo is used as a gel which is made in Mazandaran University of Medical Sciences in 60 g tubes, is applied twice a day for a month. Placebo is used as an adjunct to the main antifungal drug prescribed by dermatologist.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tooba clinic

Full name of responsible person

Yaser Nasirzadeh

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5th Floor, Shayan 3 Bldg., Ghaem 12 St., Ghaem St., Taleghani Blvd., Sari,

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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. Majid Saeedi

Street address

5th Floor, Shayan 3 Bldg., Ghaem 12 St., Ghaem St., Taleghani Blvd., Sari

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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

Ph.D.

Other areas of specialty/work

Mycology

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Person responsible for scientific inquiries

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Mazandaran University of Medical Sciences

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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

Undecided - It is not yet known if there will be 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

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

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