

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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. Wwww.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

**Age**

From **10 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to observe random allocation, the site [www.randomizer.org](http://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

##### Street address

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

##### City

Sari

##### Province

Mazandaran

##### Postal code

4817845423

##### Phone

+98 11 3325 7911

##### 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

#### Contact

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr. Maryam Moazeni

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr. Maryam Moazeni

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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