Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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 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
City
Sari
Province
Mazandaran
Postal code
4817845423
Phone
+98 11 3325 7911
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
Street address
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

Person responsible for scientific 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

Street address
Shayan 3 Bldg, Ghaem 12 St., Ghaem St., Taleghani Blvd., Sari

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Province
Mazandaran

Postal code
4817845423

Phone
+98 11 3325 7911

Email
moazeni.maryam@gmail.com

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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5th floor, Shayan 3 Bul., Ghaem 12 St, Ghaem St., Taleghani Blvd., Sari

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Province
Mazandaran

Postal code
4817845423

Phone
+98 11 3325 7911

Email
moazeni.maryam@gmail.com

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