Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

evaluation of antifungal supplement properties of zataria multiflura - loaded nanostructural lipid carriers on dermatophytosis

Protocol summary

Study aim
Determination of antifungal supplement properties of Zataria multiflora-loaded nanostructural lipid carriers on dermatophytosis .

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 80 patients. Www.randomizer.org was used to observe random allocation.

Settings and conduct
80 patients referred by a physician in Sari whose dermatophytosis 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 dermatophytosis . 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
number of patient 80, dermatophytosis 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 80 patients confirmed, 40 will be a test sample and 40 will be a control sample .Patients are divided into four groups of 20 based on gender 1. Two intervention groups, male and female with dermatophytosis, receiving thyme nano drug 2. Two comparison groups of males and females with dermatophytosis receiving placebo

Main outcome variables
Clinical criteria of dermatophytosis lesions (Itching, inflammation and scaling; mycological criteria; side effects; patients satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210611051539N2**
Registration date: **2021-12-25, 1400/10/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-25, 1400/10/04**
Update count: **0**

Registration date
2021-12-25, 1400/10/04

Registrant information

Name
Maryam Moazeni

Name of organization / entity

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Iran (Islamic Republic of)

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+98 11 3325 7911

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-04-19, 1401/01/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation of antifungal supplement properties of zataria multiflura - loaded nanostructural lipid carriers on dermatophytosis

Public title

effect of nano-zataria multiflora supplement on dermatophytosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

all patients presenting with mild- moderate dermatophytosis 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
- Care provider
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to observe random allocation, patients will divided into group A and B and simple randomization is performed individually using Random number table . Allocation concealmen is done using non transparent sealed envelopes. Specializing of even and odd codes perform on the envelop for drug and placebo and only the main researcher aware of them.

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, shayan3 Bldg, Ghaem12 st, ghaem st ,taleghani Blvd,sari

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Province

Mazandaran

Postal code

4817845423

Approval date

2021-06-07, 1400/03/17

Ethics committee reference number

IR.MAZUMS.REC.1400.230

Health conditions studied

1

Description of health condition studied

Dermatophytosis

ICD-10 code

B35.9

ICD-10 code description

Dermatophytosis, unspecified

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

evaluation of clinical symptoms such as inflammation , pruritus ,scaling and evaluation of negative direct and culture exam in 2 and4 weeks

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: for patients with dermatophytosis(exept tinea angum and tinea capitis)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 patient with dermatophytosis(except tinea angum and tinea capitis), placebo is used as a gel which is made in mazandaran university of medical science in 60g tube , 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
toba clinic
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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