Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative study of the efficacy of topical nano-emulsion fluconazole gel with its oral drug form in the treatment of dermatophytosis infections

Protocol summary

Study aim
Determination of the Effectiveness of Fluconazole Nano-Emulgel with its Oral Form in the Treatment of Dermatophytes
Design
Randomized, blinded, clinical trial with a parallel group design
Settings and conduct
A study was conducted in patients referring to Dermatology Clinic of Bouali Hospital and office in sari for 6 months. The physician and secretary were blinded.
Participants/Inclusion and exclusion criteria
Patients with cutaneous dermatophytosis
Intervention groups
Both groups of patients with cutaneous dermatophytosis receive an oral treatment group and the other receive topical treatment.
Main outcome variables
Irritation,Itching,Scalling,Erythema

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190326043113N1**
Registration date: **2019-05-09, 1398/02/19**
Registration timing: **retrospective**

Last update: **2019-05-09, 1398/02/19**
Update count: **0**
Registration date
2019-05-09, 1398/02/19

Registrant information
Name
Farnaz Rajabali
Name of organization / entity
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Iran (Islamic Republic of)
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+98 21 2675 0655
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-09-23, 1397/07/01
Expected recruitment end date
2019-09-23, 1398/07/01
Actual recruitment start date
2018-09-23, 1397/07/01
Actual recruitment end date
2019-03-20, 1397/12/29
Trial completion date
2019-04-19, 1398/01/30

Scientific title
Comparative study of the efficacy of topical nano-emulsion fluconazole gel with its oral drug form in the treatment of dermatophytosis infections

Public title
Comparative study of nano-emulsion fluconazole gel with oral form in dermatophyte treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 10 years old Patients with localized cutaneous dermatophytosis with a maximum of 3 to 4 patches Not taking topical or oral antifungal medicines from 4 weeks ago Not taking oral or topical steroids from 4 weeks ago
Exclusion criteria:
Pregnant and breastfeeding women Diabetic patients taking sulfonylureas, tolbutamide and glyburide Taking

phenytoin and Coumarin Anticoagulants onichomycosis Dermatophytosis of head and beard severe Cutaneous dermatophytosis

Age
From **10 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **40**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
we gave the doctor a specific number of two groups of medicine and a placebo, and the doctor treated the patient by random

Blinding (investigator's opinion)
Double blinded

Blinding description
As a researcher, I divided the medication and placebo into 2 groups A and B and gave the physician the right to distribute the drug among the patients without knowing which group contains topical treatment and which group contains oral treatment.

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
Central headquarters of Mazandaran University of Medical Sciences and Health Services,beginning of Valiasr highway,

City
Sari

Province
Mazandaran

Postal code
۴۸۱۵۷۳۳۹۷۱

Approval date
2018-08-18, 1397/05/27

Ethics committee reference number
Ir.mazums.rec.1398.028

Health conditions studied

1

Description of health condition studied
Cutaneous dermatophyte

ICD-10 code
B35.4

ICD-10 code description
Tinea corporis

Primary outcomes

1

Description
Scratch rate

Timepoint
Zero, second, fourth and eighth week

Method of measurement
questionnaire

Secondary outcomes

1

Description
Flaking

Timepoint
The second, fourth and eighth weeks

Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group: receivers of the topical Fluconazole Nano-emolgel, formulated in the Pharmaceutical Laboratory of the Faculty of Pharmacy, and an oral placebo containing filled with avicel capsules.Patients receive medication for four weeks and follow up every two weeks. After discontinuation of the drug, after four weeks of recurrence of disease is examined. The topical product is given twice daily and oral capsule is given weekly.

Category
Treatment - Drugs

2

Description
Control group: receivers of the topical placebo, and an oral fluconazole 150 miligram capsules.Patients receive medication for four weeks and follow up every two weeks. After discontinuation of the drug, after four weeks of recurrence of disease is examined. The topical product

is given twice daily and oral capsule is given weekly

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Bouali Sari Hospital

Full name of responsible person

Farnaz Rajabali

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Emam square, Pasdaran boulvard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid saeedi

Street address

17th kilometer of darya road

City

Sari

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Mazandaran

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majsaeedi@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sari 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

Farnaz Rajabali

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Outcome of main information
When the data will become available and for how long
From 1398
To whom data/document is available
All the researchers in this field
Under which criteria data/document could be used
No further analysis is allowed on the data
From where data/document is obtainable
corresponding author
What processes are involved for a request to access data/document
Send a requested email to the corresponding author
Comments