

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 21 2675 0655

Email address

rajabali.farnaz@yahoo.com

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

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

phenytoin and Coumarin Anticoagulants onychomycosis
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

lr.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
Street address
Emam square, Pasdaran boulevard
City
Sari
Province
Mazandaran
Postal code
624304840015
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rajabali.farnaz@yahoo.com

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
Postal code
۴۸۱۵۷۳۳۹۷۱
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+98 11 3448 4800
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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
Street address
15th number, 13th block, qaderi alley, Sharifi square, Pasdaran,
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Farnaz

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