

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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

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

Phone

+98 21 2675 0655

Email

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

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Phone

+98 11 3448 4800

Email

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,

City

Sari

Province

Mazandaran

Postal code

624304840015

Phone

+98 212670655

Email

rajabali.farnaz@yahoo.com

Person responsible for scientific 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

Number 15, block 13, Qaderi alley, Sharifi square, Pasdaran

City

Tehran

Province

Tehran

Postal code

624304840015

Phone

+98 92126750655

Email

rajabali.farnaz@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Farnaz

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Number 15, block 13, Qaderi alley, Sharifi square,
Pasdaran

City

tehran

Province

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624304840015

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+98 92126750655

Email

rajabali.farnaz@yahoo.com

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