

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effectiveness of a silicone gel containing antifungal compounds in patients with tinea corporis

Protocol summary

Study aim

Investigating the effectiveness of a silicone gel containing antifungal compounds terbinafine and thymol on patients with tinea corporis

Design

The population size is 100 patients and they are divided into two parallel groups (intervention and control). This trial is randomized and double-blind. The block randomization method will be used in Research Randomizer and 25 blocks with size of 4 will be created.

Settings and conduct

Men and women with fungal skin infections will be referred to Dr. Kavooosi's Dermatology Clinic after confirmation in the Mycology Department of Mahdieh Clinic. If eligible, they will be enrolled in the study and randomly assigned to the intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Less than 7 days have passed since the onset of their illness; be positive for dermatophyte filaments in 10% KOH mount and less than 20% of their body surface area is involved; erythema, scaling, and itching scores are at least two. Exclusion criteria: Use of corticosteroids, antibiotics, or antifungal treatments topically or systemically during and up to four weeks before start of study

Intervention groups

Intervention group 1: Silicone gel containing thymol and terbinafine (two antifungal compounds, 1% terbinafine and 3% thymol which is prepared at the Faculty of Pharmacy, Kermanshah University of Medical Sciences) applied topically twice a day for 14 days. Intervention group 2: This is the control group and they received terbinafine cream (Lamisil, Novartis Co., 1% drug) cream twice daily for 14 days.

Main outcome variables

Mycological symptoms; Erythema at infected area; Scaling at the infected area; Itching/Burning at infected area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240923063136N3**

Registration date: **2025-04-25, 1404/02/05**

Registration timing: **prospective**

Last update: **2025-04-25, 1404/02/05**

Update count: **0**

Registration date

2025-04-25, 1404/02/05

Registrant information

Name

Sara Darakhshan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-10-22, 1404/07/30

Expected recruitment end date

2026-10-22, 1405/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of a silicone gel containing antifungal compounds in patients with tinea corporis

Public title

Evaluating effectiveness of an antifungal gel in patients with tinea corporis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have been ill for fewer than 7 days will be included in the study. All patients who are positive for dermatophyte filaments on 10% KOH mount and have less than 20% of their body surface area involved will be included in the study. No other skin disease should be reported. Erythema, scaling rash, and itching should be at least 2 numbers.

Exclusion criteria:

Patients with diabetes, HIV, diseases and immune system problems will not be included in the study. Patients with a history of hypersensitivity reactions to terbinafine were not included in the study. Individuals who are using topical or systemic corticosteroids, antibiotics, or antifungal treatments, or have used them within four weeks prior to the start of the study, will not be included in the study. Pregnant, lactating women, or those planning to become pregnant were not included in the study.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with a block size of 4 will be used for the two groups. A third person who is not involved in the patient recruitment and evaluation process will create the random sequence using the Research Randomizer. Each patient will be given a unique code that can be generated on this site. Therefore, the individuals involved in the study will not know which group the next person will be assigned to, nor will they be aware of the random sequence; only the statistical consultant will have knowledge of the random sequence, and the codes will remain with him.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding is not possible because Lamisil is a cream and differs from silicone gel in its appearance. The statistical consultant who provided the data analysis is aware of the groups and codes. The person evaluating the results is not aware of the codes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

University Street, Parastar Blvd.

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2025-01-27, 1403/11/08

Ethics committee reference number

IR.KUMS.REC.1403.594

Health conditions studied

1

Description of health condition studied

Skin fungal infection

ICD-10 code

B35.4

ICD-10 code description

Tinea corporis

Primary outcomes

1

Description

Symptoms of fungal infection

Timepoint

Before intervention (day 0), and after intervention (day 15)

Method of measurement

Potassium hydroxide (KOH) preparation test

Secondary outcomes

1

Description

Erythema at the site of infection

Timepoint

Before intervention (day 0), and after intervention (day 15)

Method of measurement

Visual assessment

2

Description

Scaling at the site of infection

Timepoint

Before intervention (day 0), and after intervention (day 15)

Method of measurement

Visual assessment

3

Description

Burning/itching sensation at the site of infection

Timepoint

Before intervention (day 0), and after intervention (day 15)

Method of measurement

visual analogue scale (VAS)

Intervention groups

1

Description

Intervention group 1 will receive silicone gel containing two antifungal compounds, terbinafine and thymol. The amount of terbinafine is 1% and the amount of thymol is 3%. This is the gel that we plan to prepare during our experiments (at Faculty of Pharmacy, Kermanshah University of Medical Sciences). Duration of application will be two weeks, applied to the site of infection every day, twice a day. Outcomes will be assessed on day 0 (before the start of the interventions) and day 15 (the day after the end of the interventions).

Category

Treatment - Drugs

2

Description

Control group: In this group, patients receive commercially available terbinafine 1% cream (Lamisil, NOVARTIS Co). Duration of application will be two weeks, applied to the site of infection every day, twice a day. Outcomes will be assessed on day 0 (before the start of the interventions) and day 15 (the day after the end of the interventions).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh Clinic

Full name of responsible person

Hossein Kavosi

Street address

Mahdieh Blvd., Kermanshah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Zohreh Rahimi

Street address

Building No. 2, Beheshti Blvd., Kermanshah city

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research_it@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Cyrus Jalili

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Anatomy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Razi University

Full name of responsible person

Sara Darakhshan

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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Assistant professor

Latest degree

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Other areas of specialty/work

Biomaterials

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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

Undecided - It is not yet known if there will be a plan to make this available

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

Not applicable

Data Dictionary

Not applicable