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. Kavoosi'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

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Iran (Islamic Republic of)

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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

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Building No. 2, Beheshti Blvd., Kermanshah city

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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

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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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