

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effect of film-forming spray containing terbinafine (DermatoTreat) in the dermatophytosis treatment, A randomized double-blind clinical trial

#### Protocol summary

##### Study aim

A randomized, double-blind clinical trial, investigating the effectiveness, tolerance, and consumer acceptability of Dermatotrit topical antifungal spray (a product of Parsa Polymer Biotechnology Co., Ltd.) versus terbinafine ointment 1% in the treatment of Tinea pedis and Tinea versicolor

##### Design

Randomized, two arm parallel, double blinded, phase 3 clinical trial with two groups (case and control) on 98 patients. Randomization is done using randomly modified blocks created by the software (block size = 4).

##### Settings and conduct

Volunteer patients will be systematically randomly treated with 1% terbinafine cream and Dermatotrit spray. Patients are evaluated at the beginning and 1, 2 and 4 weeks after the treatment. The place of the study is the Dermatology Department of Shahid Faghihi Hospital and the Medical Mycology Department of the Faculty of Medicine. This study will be a double-blind randomized clinical trial (researcher and participants).

##### Participants/Inclusion and exclusion criteria

Entry conditions: Patients with dermatophytosis infection of the body or feet, which have been confirmed based on clinical symptoms observed by a dermatologist and mycological diagnostic tests (direct test and culture).  
Non entry conditions: Tinea pedis patients of moccasin type, Tinea capitis, Tinea with an extent of more than 20% and users of oral antifungal drugs in the two weeks before or during the study

##### Intervention groups

Case: treatment with Dermatotrit spray Patients receive Dermatotrit experimental drug spray for daily topical treatment (twice daily) for upto 4 weeks. Control: treatment with the standard Terbinafine cream 1% Patients receive Terbinafine cream 1% for daily topical treatment (twice daily) for upto 4 weeks.

#### Main outcome variables

Effective treatment (fungal treatment and minimal symptoms)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230816059161N1**

Registration date: **2023-12-25, 1402/10/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-12-25, 1402/10/04**

Update count: **0**

##### Registration date

2023-12-25, 1402/10/04

##### Registrant information

##### Name

Kamiar Zomorodian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3234 9411

##### Email address

zomorodian@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-06, 1402/08/15

##### Expected recruitment end date

2024-11-05, 1403/08/15

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of film-forming spray containing terbinafine (DermatoTreat) in the dermatophytosis treatment, A randomized double-blind clinical trial

**Public title**

Investigating the effect of DermatoTreat spray in the treatment of dermatophytosis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

All the dermatophytosis patients who were diagnosed by physical exam by doctor or by routine mycological methods Availability for the duration of the study (6 weeks) Male or female, 18 years or older Willingness to follow the study protocol Not taking systemic antifungal drugs in the last month Not using topical anti-fungal drugs or anti-fungal shampoo in 2 weeks before treatment Insensitivity to terbinafine Informed consent

**Exclusion criteria:**

Moccasin-type tinea pedis Tinea capitis , tinea with an area of more than 20% of the body Tinea resistant to previous treatments including oral treatment and Tinea incognito Severe maceration of interdigital spaces Severe fissuring Prescribing or taking oral antifungal medication in the two weeks before or during the study History of dry feet, cracks, fissures Concomitant onychomycosis Serous discharge or pus Concomitant immunosuppressive or antimicrobial therapy Failure to respond to treatment Drug allergy Failure to cooperate with the doctor Pregnant and lactating women

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**

Target sample size: **98**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

An independent investigator, not directly involved in the trial, performed the randomization using permuted randomized blocks created by the software (block size = 4). Allocation concealment will also be performed by an independent investigator using sequentially numbered sealed, opaque envelopes.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients and physicians will be blinded to treatment group assignment throughout the study. Patients in the treatment group will be treated with an effective spray and an ineffective ointment, and patients in the control group will be treated with an effective ointment and an ineffective spray. The appearance, size, color and smell of ointments and sprays will be completely similar in both groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Iran National Committee for Ethics in Biological Research

**Street address**

Shiraz University of Medical Science, Karim Khan Zand Ave.

**City**

Shiraz

**Province**

Fars

**Postal code**

71348-14336

**Approval date**

2023-08-29, 1402/06/07

**Ethics committee reference number**

IR.SUMS.REC.1402.261

**Health conditions studied****1****Description of health condition studied**

Dermatophytosis

**ICD-10 code**

B35

**ICD-10 code description**

Dermatophytosis

**Primary outcomes****1****Description**

Effective treatment (fungal treatment and minimal symptoms)

**Timepoint**

In the beginning, 1, 2 and 4 weeks after the initiation of therapy

**Method of measurement**

Microscopic examination (direct smear exam) and clinical evaluation that is based on a total of 6 symptoms (skin peeling, vesiculation, erythema, fissure, soaking and itching) which is recorded by the physician.

## Secondary outcomes

### 1

#### Description

The amount of side effects

#### Timepoint

In the beginning, 1, 2 and 4 weeks after beginning of therapy

#### Method of measurement

To check the safety of the treatment, we will calculate the amount of side effects as well as serious side effects and compare them between the two arms of the study using chi-square tests to check if there is a statistically significant difference or not.

### 2

#### Description

Effective treatment (fungal treatment and minimal symptoms)

#### Timepoint

4 weeks after beginning of therapy

#### Method of measurement

Negative mycological microscopic test (direct) and clinical evaluation that is based on a total of 6 symptoms (skin peeling, vesiculation, erythema, fissure, soaking and itching) which is recorded by the doctor.

### 3

#### Description

Patient satisfaction score

#### Timepoint

At the end of the treatment period

#### Method of measurement

Patients complete a short survey in the form of a questionnaire about their perception of the tolerability, effectiveness and comfort of the treatment on a five-point scale, where 1 = poor, 2 = fair, 3 = good, 4 = very good, 5 = great, or they may respond with "no answer/prefer not to say". Scores for each treatment will be calculated and compared.

### 4

#### Description

Self-reported patient compliance

#### Timepoint

At the end of the treatment period

#### Method of measurement

In the questionnaire, patients are asked to estimate how many doses they have missed. Possible answers include none, 1-2, 3-4, 5-6, 7-8, or 9 or more. It shows whether there is a significant difference in the probability of adherence of patients to a treatment regimen or not.

## Intervention groups

### 1

#### Description

Intervention group: treatment with DermatoTreat spray. Patients receive the developed Dermatotrit spray containing 1% Terbinafine Hydrochloride manufactured by Parsa Biotechnology Biotechnology Company for daily topical treatment (twice a day) for 4 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Treatment with the standard Terbinafine cream 1%. Patients receive terbinafine ointment 1% (under the trade name Binafin 1%) manufactured by Tehran Chemical Factory for daily (twice) topical treatment for 4 weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dermatology ward of Shahid Faghihi hospital

##### Full name of responsible person

Dr. Mahdi Ghahartars

##### Street address

Karim khan Zand Ave., Shahid Faghihi hospital

##### City

Shiraz

##### Province

Fars

##### Postal code

۷۱۳۴۸۴۶۱۱۴

##### Phone

+98 21 3235 1087

##### Fax

##### Email

FaghihiHsp@Sums.ac.ir

##### Web page address

<https://faghihi.sums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Hashem Hashempur

##### Street address

Karim khan Zand Ave., Shiraz University of Medical Science

##### City

Shiraz  
**Province**  
Fars  
**Postal code**  
71348-14336  
**Phone**  
+98 71 3230 5410  
**Email**  
info@sums.ac.ir  
**Web page address**  
https://sums.ac.ir/  
**Grant name**  
Shiraz University of Medical Sciences  
**Grant code / Reference number**  
28330  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shiraz University of Medical Sciences  
**Proportion provided by this source**  
50  
**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

## 2

**Sponsor**  
**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Dr Pedram Ebrahimnejad  
**Street address**  
Valie-Asr Blvd., Mazandaran University of Medical Science  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4815733971  
**Phone**  
+98 11 3304 4000  
**Email**  
ravabetomoomi@mazums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Mazandaran University of Medical Sciences  
**Proportion provided by this source**  
50  
**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**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Kamiar Zomorodian  
**Position**  
Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Mycology  
**Street address**  
School of Medicine, Shiraz University of Medical Science, Emam Hosein square, Karim khan Zand Ave.  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7134845794  
**Phone**  
+98 71 3230 5887  
**Email**  
zomorodian@sums.ac.ir

## **Person responsible for scientific inquiries**

**Contact**  
**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Kamiar Zomorodian  
**Position**  
Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Mycology  
**Street address**  
School of Medicine, Shiraz University of Medical Science, Emam Hosein square, Karim khan Zand Ave.  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7134845794  
**Phone**  
+98 71 3230 5887  
**Email**  
zomorodian@sums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Kamiar Zomorodian

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Mycology

**Street address**

School of Medicine, Shiraz University of Medical  
Science, Emam Hosein square, Karim khan Zand Ave.

**City**

Shiraz

**Province**

Fars

**Postal code**

7134845794

**Phone**

+98 71 3230 5887

**Email**

zomorodian@sums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

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

**Data Dictionary**

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

**Title and more details about the data/document**

The obtained results will be published in the form of articles and specialized congresses.

**When the data will become available and for how long**

One year after the results are published

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Data can be obtained for the purpose of health promotion after sending a written request from the principal investigator.

**From where data/document is obtainable**

A written request for access to information should be sent to the email of the corresponding author or principal investigator.( Dr. Kamiar Zomorodian, zomorodian@sums.ac.ir)

**What processes are involved for a request to access data/document**

The request will be reviewed by the main researcher and if approved, will be sent to the applicant.

**Comments**