# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**
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Iran (Islamic Republic of)
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**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**
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**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
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Dr Mohammad Hashem Hashempur
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**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
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Valie-Asr Blvd., Mazandaran University of Medical Science
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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**
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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**
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**Latest degree**
Ph.D.

**Other areas of specialty/work**
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## 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**