

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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Shiraz University of Medical Science, Karim Khan Zand Ave.

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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

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Karim khan Zand Ave., Shahid Faghihi hospital

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Sponsors / Funding sources

1

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Name of organization / entity

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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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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
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Full name of responsible person
Kamiar Zomorodian
Position
Professor
Latest degree
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Other areas of specialty/work
Mycology
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Person responsible for updating data

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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