Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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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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
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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
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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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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
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Person responsible for updating data

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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