Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the Efficacy and Safety of Adding Topical BT DERMA to Standard Therapy versus Standard Therapy Alone in Patients with Dermatophytosis

Protocol summary

Study aim

To compare the safety and efficacy of BT DERMA plus standard treatment versus standard treatment alone in dermatophytosis patients.

Design

This is a non-randomized, phase 2/3 clinical trial on 30 patients with dermatophytosis. All patients will receive oral itraconazole 200 mg once daily and ketoconazole 2% antifungal shampoo. For topical treatment, one lesion will receive clotrimazole 1% cream alone, while another lesion will receive both clotrimazole 1% and BT DERMA creams simultaneously.

Settings and conduct

Patient recruitment will be conducted at the specialized dermatology clinic of Dr. Khodashenas, the principal investigator. The study will include 30 patients, and no blinding will be performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmed fungal skin infection (dermatophytosis); At least two lesions in two distinct anatomical sites. Exclusion criteria: Current or prior immunosuppressive medication use; Secondary bacterial infection; Recent or concurrent antifungal use; Concomitant drugs interfering with itraconazole absorption or metabolism

Intervention groups

Intervention group 1: one lesion on one side of the limb will receive clotrimazole 1% cream twice daily for at least 4 weeks, continuing until improvement is observed. Intervention group 2: Another lesion on the opposite side of the same limb will receive both clotrimazole 1% cream and BT DERMA cream twice daily for at least 4 weeks, continuing until improvement is observed. If multiple lesions are present, the remaining lesions will be treated with clotrimazole 1% cream only.

Main outcome variables

The degree of erythema, itching, and scaling of skin lesions; KOH test result

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240304061158N6**
Registration date: **2026-07-07, 1405/04/16**
Registration timing: **prospective**

Last update: **2026-07-07, 1405/04/16**
Update count: **0**

Registration date

2026-07-07, 1405/04/16

Registrant information

Name

fariba nemati

Name of organization / entity

Behpad Teb Iranian

Country

Iran (Islamic Republic of)

Phone

+98 21 6642 6890

Email address

info@behpadti.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-08-23, 1405/06/01

Expected recruitment end date

2026-08-23, 1405/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Efficacy and Safety of Adding Topical BT DERMA to Standard Therapy versus Standard Therapy Alone in Patients with Dermatophytosis

Public title

Efficacy of BT DERMA product in the treatment of cutaneous fungal infections

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of dermatophytosis (fungal skin infection) by positive potassium hydroxide (KOH) test. Subjects who have at least two lesions at two different anatomical locations Provision of informed consent to participate in the study

Exclusion criteria:

Pregnant and lactating women Patients with renal, hepatic, or heart failure History of hypersensitivity to the study medications Patients who have received systemic immunosuppressive drugs within two weeks prior to study entry Patients with secondary bacterial infection Patients taking medications that affect the absorption (e.g., antacids) or metabolism (e.g., anticonvulsants) of itraconazole

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

Dermatophytosis lesion

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

The study will be conducted using a split-body design.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahed University

Street address

Shahed University, opposite Holy shrine of Imam Khomeini, Khalij Fars Expressway

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2025-12-08, 1404/09/17

Ethics committee reference number

IR.SHAHED.REC.1404.004

Health conditions studied

1

Description of health condition studied

Skin fungi (dermatophytes)

ICD-10 code

B35

ICD-10 code description

Dermatophytosis

Primary outcomes

1

Description

Erythema

Timepoint

Clinical evaluation was performed on days 0, 7, 14, 21, and 28 after study initiation.

Method of measurement

Visual Analogue Scale

2

Description

Pruritus

Timepoint

Clinical evaluation was performed on days 0, 7, 14, 21, and 28 after study initiation.

Method of measurement

Visual Analogue Scale

3

Description

Scaling

Timepoint

Clinical evaluation was performed on days 0, 7, 14, 21, and 28 after study initiation.

Method of measurement

Visual Analogue Scale

4

Description
KOH test result
Timepoint
Days 0 and 28 after study initiation
Method of measurement
Performing KOH test

Secondary outcomes

1

Description
Safety
Timepoint
7rd, 14th, 21th, 28nd days after starting the study
Method of measurement
Doctor examination and patient report

Intervention groups

1

Description
Intervention group: Patients will receive oral itraconazole 200 mg once daily plus ketoconazole 2% shampoo (with each bath, at least twice and up to five times weekly). For topical treatment, one lesion on one side of the limb will receive BT DERMA and clotrimazole 1% cream twice daily for at least 4 weeks, continuing until improvement is observed.
Category
Treatment - Drugs

2

Description
Control group: Patients will receive oral itraconazole 200 mg once daily plus ketoconazole 2% shampoo (with each bath, at least twice and up to five times weekly). For topical treatment, one lesion on one side of the limb will receive clotrimazole 1% cream twice daily for at least 4 weeks, continuing until improvement is observed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Khodashenas dermatology clinic
Full name of responsible person
Zohreh Khodashenas
Street address
BRT 32th station, Valiasr Street
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2

Recruitment center
Name of recruitment center
Mostafa Khomeini Hospital
Full name of responsible person
Zohreh Khodashenas
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No. 9, Italia Street., Felelestin Street, Keshavarz Boulevard, Valiasr Square, Tehran
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Sponsors / Funding sources

1

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Behpad Teb Iranian
Full name of responsible person
Fariba Nemati
Street address
Unit 22, Fanavaran Building, Danesh 4, Pardis Technology Park, 20th Kilometer of Damavand Road, Tehran, Iran
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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
Behpad Teb Iranian
Proportion provided by this source
85
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

2

Sponsor
Name of organization / entity
Shahed university Immune Response Regulation Research Center
Full name of responsible person
Azade Rashidi
Street address
No 1471, Immunoregulation Research Center, Research Centers of Shahed University, North Kargar Ave, Tehran, Iran.
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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
Shahed university Immune Response Regulation Research Center
Proportion provided by this source
15
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
Immunoregulation Research Center
Full name of responsible person
Azadeh Rashidi
Position
master of science
Latest degree
Master
Other areas of specialty/work
Immunology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Ethical consideration about patient information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
After publishing the final results, the study protocol, statistical analyzes and the informed consent form will be shared without mentioning the names of the individuals.
When the data will become available and for how long
Access starts 6 months after the results are published
To whom data/document is available
Domestic researchers
Under which criteria data/document could be used
To conduct review studies or advanced statistical analysis and bioinformatics
From where data/document is obtainable
Azadeh Rashidi (project coordinator-Immunoregulation research center-Shahed university) azadehashidi025@gmail.com
What processes are involved for a request to access data/document
Submitting a request to the executor of the project, Mrs. Dr. khodashenas,Referral to the head of the center Shahed University research, Obtain university approval,Provision of data
Comments