

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Not yet recruiting

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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Tehran

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1418863981

Phone

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Email

zohrehkhodashenas@gmail.com

2

Recruitment center

Name of recruitment center

Mostafa Khomeini Hospital

Full name of responsible person

Zohreh Khodashenas

Street address

No. 9, Italia Street., Felelestin Street, Keshavarz Boulevard, Valiasr Square, Tehran

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Email

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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Web page address

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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 addressNo 1471, Immunoregulation Research Center,
Research Centers of Shahed University, North Kargar
Ave, Tehran, Iran.**City**

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Email

immunoreg@shahed.ac.ir

Web page address<https://irrc.shahed.ac.ir>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceShahed 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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a.rashidi@shahed.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Skin clinic of Dr. Khodashenas

Full name of responsible person

Zohreh Khodashenas

Position

Dermatologist

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data**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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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