

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Sep 2026

### The effect of terbinafine and itraconazole on the treatment of tinea incognita

#### Protocol summary

##### Study aim

Investigation the effect of terbinafine and itraconazole on the treatment of tinea incognita in patients referring to the Haj Daei clinic of Kermanshah

##### Design

This study is a clinical trial on 50 eligible patients with tinea incognita which will be randomly assigned into two intervention groups.

##### Settings and conduct

This study will be conducted on 50 patients with primary diagnosis of tinea incognita coming to Haj Daei clinic of Kermanshah city. Participants will be assigned non-randomly into intervention groups. The study is not blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: More than 15 years; Local or systemic corticosteroid use for fungal infection  
Exclusion criteria: Immune system weakness; History of allergy to antifungal drugs; Breastfeeding and pregnancy

##### Intervention groups

The first intervention group will receive 250mg Terbinafine tablets for 4 weeks daily. The second intervention group will receive 100 mg of itraconazole capsule for 4 weeks daily.

##### Main outcome variables

Itching, redness of the skin, scaling

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20090515001906N12**

Registration date: **2018-04-16, 1397/01/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-04-16, 1397/01/27**

Update count: **0**

##### Registration date

2018-04-16, 1397/01/27

##### Registrant information

###### Name

Ali Ebrahimi

###### Name of organization / entity

Kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1823 3862

###### Email address

aebrahimi@kums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-03-25, 1397/01/05

##### Expected recruitment end date

2018-05-26, 1397/03/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of terbinafine and itraconazole on the treatment of tinea incognita

##### Public title

The effect of terbinafine and itraconazole on the treatment of topical skin fungal infection

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

More than 15 years Local or systemic corticosteroid use

for fungal infection  
**Exclusion criteria:**  
Immune system weakness History of allergy to antifungal drugs Taking anticoagulant drugs such as heparin and warfarin Pregnancy Lactation and culture-negative

#### Age

From **15 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **50**

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

##### Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti,

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

#### Approval date

2016-12-14, 1395/09/24

#### Ethics committee reference number

kums.rec.1395.537

## Health conditions studied

### 1

#### Description of health condition studied

Tinea incognito

#### ICD-10 code

B35.9

#### ICD-10 code description

Dermatophytosis, unspecified

## Primary outcomes

### 1

#### Description

Itching

#### Timepoint

The beginning of the study; The second week; The fourth; The eighth and twelfth

#### Method of measurement

By asking the patient

### 2

#### Description

Skin redness

#### Timepoint

The beginning of the study; The second week; The fourth; The eighth and twelfth

#### Method of measurement

Physician observation

### 3

#### Description

Flaking

#### Timepoint

The beginning of the study; The second week; The fourth; The eighth and twelfth

#### Method of measurement

Physician observation

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first intervention group will receive 250mg Terbinafine tablets for 4 weeks daily

#### Category

Treatment - Drugs

### 2

#### Description

. The second intervention group will receive 100 mg of isotretinoic acid capsule for 4 weeks daily

#### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Haj Doei Clinic

**Full name of responsible person**

Sepideh Hamzehei

**Street address**

Mostafa Emami Boulevard, Golestan Quarter

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714643451

**Phone**

+98 83 3835 7070

**Email**

sepidehhamzehei@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Farid Najafi

**Street address**

Vice Chancellor for Research Affairs, Kermanshah  
University of Medical Sciences, Building No.2, Shahid  
Beheshti

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**Email**

fnajafi@kums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah University of Medical Sciences

**Proportion provided by this source**

100

**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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Sepideh Hamzehei

**Position**

Medical Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

School of Medicine, parastar boulevard

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**Fax****Email**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Ali Ebrahimi

**Position**

Member of Scientific Board of Kermanshah University  
of Medical Sciences

**Latest degree**

Specialist

**Other areas of specialty/work**

Others

**Street address**

School of Medicine, parastar boulevard

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Medical Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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**Postal code**

6715847141

**Phone**

+98 83 3427 4618

**Email**

sepidehhamzehei@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The main outcomes of the study will be shared.

**When the data will become available and for how long**

2 months

**To whom data/document is available**

If requested, results will be made available to other academic researchers

**Under which criteria data/document could be used**

Collected data is confidential and will not be shared with anyone else

**From where data/document is obtainable**

To receive the documentation, email send for update manager

**What processes are involved for a request to access data/document**

In a 15-day period, the documents will be sent e-mail

**Comments**