# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 Daee 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 Daee clinic of Kermanshah city. Participants will be 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
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Iran (Islamic Republic of)
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**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

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## 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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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

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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

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Others

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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**
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**