

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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)

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+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

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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

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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

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

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Full name of responsible person

Dr. Ali Ebrahimi

Position

Member of Scientific Board of Kermanshah University
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Latest degree

Specialist

Other areas of specialty/work

Others

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Person responsible for updating data

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Name of organization / entity

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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