

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of oral terbinafin and griseofulvin in the treatment of tinea capitis

#### Protocol summary

##### Summary

The objective of this randomized, trial is comparing the treatment effects and complications of oral terbinafin and griseofulvin in 50 patients suffering from tinea capitis. In this study, patients presented with tinea capitis and documented by KOH or culture were included in study. Patients with Pregnancy:infantile: breastfeeding: sensitivity to terbinafin and griseofulvin and previous treatment with antifungal drugs were excluded from the study. After taking the written informed consent, demographic and clinical data were recorded in a questionnaire. In one group of patients, treatment with oral griseofulvin 10 mg/kg and in another group,treatment with oral terbinafin 5 mg/kg was prescribed for 1 month. Patients were followed up for outcome and probable complications at the end of the second week and first and second month. Finally,the treatment outcomes including cure rate and complications such as persistent infection and recurrence were compared by appropriate statistical test in two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201704056403N8**  
Registration date: **2017-11-12, 1396/08/21**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-11-12, 1396/08/21

##### Registrant information

###### Name

Hossein Kavoussi

###### Name of organization / entity

Kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1837 5424

###### Email address

hkawosi@kums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Kermanshah University of medical sciences

###### Expected recruitment start date

2017-09-10, 1396/06/19

###### Expected recruitment end date

2018-02-20, 1396/12/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Comparison of oral terbinafin and griseofulvin in the treatment of tinea capitis

###### Public title

Treatment of tinea capitis by oral terbinafin and griseofulvin

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: Tinea documented by laboratory assessment Exclusion criteria: Pregnancy: infancy, breastfeeding: sensitivity to terbinafin and griseofulvin: previous treatment with antifungal drugs

###### Age

From **2 years** old to **70 years** old

###### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 50

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

### 1

#### Registry name

NO

#### Secondary trial Id

NO

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Kermanshah University of  
Medical Sciences

##### Street address

Shahid Beheshty Blvd

##### City

Kermanshah

##### Postal code

#### Approval date

2016-11-23, 1395/09/03

#### Ethics committee reference number

KUMS.REC.1395.512

## Health conditions studied

### 1

#### Description of health condition studied

Tinea capitis

#### ICD-10 code

L00-L99

#### ICD-10 code description

B35-B49

## Primary outcomes

### 1

#### Description

Treatment of tinea capitis

#### Timepoint

The end of 2th week, 1th, 2th and 3th months

#### Method of measurement

clinical observation and laboratory assesment

## Secondary outcomes

### 1

#### Description

Recurrence

#### Timepoint

The end 1 week, 1th, 2th and 3th months

#### Method of measurement

Clinical observation and labratory assesmsnt

### 2

#### Description

Permanent hair loss

#### Timepoint

The end 1 week, 1th, 2th and 3th months

#### Method of measurement

Clinical observation

## Intervention groups

### 1

#### Description

In one group treatment with oral grisorfulvin In other  
group treatment with oral terbinafin

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hajdaie clinic

##### Full name of responsible person

Hossein Kavoussi

##### Street address

Golestan blvd

##### City

Kermanshah

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research of Kermanshah  
University of Medical Sciences

##### Full name of responsible person

Dr Behrouz Hamzeh

**Street address**

Department of Vice Chancellor for reaserch and technology,Shahid Beheshty Blvd

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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**

Vice Chancellor for research of Kermanshah University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr Hossein Kavoussi

**Position**

Associate Professour

**Other areas of specialty/work**

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Reza Kavoussi

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Medical Student

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Sayyad shirazy street, medical school

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00

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**Web page address**

**Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*