Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of oral terbinafin and grisofulvin 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 grisofulvin in 50 patients suffering from tinea capitis. In this study, patients presented with tinea capitisl and documented by KOH or culture were included in study. Patients with Pregnancy:infantile: breastfeeding: sensitivity to terbinafin and grisofulvin 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 grisofulvin 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
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Iran (Islamic Republic of)
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+98 83 1837 5424
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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 grisofulvin in the treatment of tinea capitis

Public title

Treatment of tinea capitis by oral terbinafin and grisofulvin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Tinea documented by laboratory assessment Exclusion criteria: Pregnancy: infancy, breastfeeding: sensitivity to terbinafin and grisofulvin: 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 Scienses
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 grisofulvin 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

City

Kermanshah

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

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Reza Kavoussi

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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