Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the therapeutic efficacy of Terbinafine and Ketoconazole in treatment of Tinea Versicolor

Protocol summary

Summary

Because of side effect of oral treatment and drug resistance, we decided to compare the therapeutic efficacy of topical Terbinafine versus topical Ketoconazole for treatment of Tinea Versicolor. Material & methods: Sixty nine patients with a clinical diagnosis of Pityriasis versicolor confirmed by microscopic potassium hydroxide (KOH) examination entered the study. Patients randomly assigned to one of 2 treatment groups: 35 patients in Terbinafine group, treated by Terbinafine 1% once daily for 2 weeks and 34 patients in Ketoconazole group, treated with Ketoconazole 2% once daily for 2 weeks. Patients were followed up at monthly intervals for 3 months and recurrence and cure rates were calculated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903194128N1**
Registration date: **2010-09-09, 1389/06/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-09-09, 1389/06/18

Registrant information

Name

Majid Rostami

Name of organization / entity

Ardebil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 1224 6687

Email address

m.rostami@arums.ir

Recruitment status

Recruitment complete

Funding source

Ardebil University of Medical Sciences

Expected recruitment start date

2007-03-21, 1386/01/01

Expected recruitment end date

2008-03-20, 1387/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the therapeutic efficacy of Terbinafine and Ketoconazole in treatment of Tinea Versicolor

Public title

Comparing the therapeutic efficacy of Terbinafine and Ketoconazole in treatment of Tinea Versicolor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient with Tinea Versicoler and positive smear. Exclusion criteria: pregnancy, sensitivity to Ketoconazole and Terbinafihne, receiving antifungoal drugs during 1 month ego, liver disease.

Age

From **16 years** old to **37 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size
Target sample size: **69**
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

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Islamic Azad University of Ardabil
Street address
Basij squar
City
Ardabil
Postal code
5615778511
Approval date
2008-03-03, 1386/12/13
Ethics committee reference number
186

Health conditions studied

1

Description of health condition studied
Tinea Versicolor
ICD-10 code
L00-L08
ICD-10 code description
Infections of the skin and subcutaneous tissue

Primary outcomes

1

Description
cilinical improvment
Timepoint
1 month
Method of measurement
cilinical observation

Secondary outcomes

1

Description
drug compilications.
Timepoint
2 weak post treatment and monthly intervals for 3 months .
Method of measurement
cilinical observation

Intervention groups

1

Description
Ketoconazole group: Ketoconazole 2% once daily for 2 weeks
Category
Treatment - Drugs

2

Description
Terbinafine group: Terbinafine 1% once daily for 2 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam hospital
Full name of responsible person
Majid Rostami
Street address
Assistant prof., Ardabil university of medical sciences
City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University of Ardabil
Full name of responsible person
Seiied Saeid Hashemein
Street address
Basij square
City
Ardabil
Grant name
عمومی
Grant code / Reference number
161
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Islamic Azad University of Ardabil

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
Ardabil University of Medical Sciences

Full name of responsible person
Dr Majid Rostami

Position
Assistant prof, Dermatologist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Assistant prof

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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