

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 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 Versicolor and positive smear. Exclusion criteria: pregnancy, sensitivity to Ketoconazole and Terbinafine, receiving antifungal drugs during 1 month ago, 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 complications.

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
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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