

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of topical terbinafine and ketoconazole in pityriasis versicolor

Protocol summary

Summary

The main aim of this study: efficacy of topical terbinafine and ketoconazole in pityriasis versicolor (rct -single blind) Inclusion criteria are: KOH positive ; involvement of less than 10% of the body surface by the lesions. Exclusion criteria are: Extensive involvement of the skin ; topical or systemic antifungal therapy; and use of steroid or antibiotic within the last month before starting the study The samples will be examined microscopically for the presence of mycelium by a pathologist if the smears are positive for mycelium. Sample size in study 100 patients they will be allocated to 2 groups randomly. Intervention group will use t terbinafin hydrochloride 1% cream.the creams are used topically twice a day for 2 weeks. . determined clinically based on observation of signs and symptoms. Itching, scaling and redness are the clinical

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107184808N4**

Registration date: **2011-11-13, 1390/08/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-11-13, 1390/08/22

Registrant information

Name

Mozhdeh Zarei

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 1613 1278

Email address

mozh.zarei@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2010-04-19, 1389/01/30

Expected recruitment end date

2011-10-23, 1390/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of topical terbinafine and ketoconazole in pityriasis versicolor

Public title

Versicolor Treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are:Age above 14 years; KOH positive ; involvement of less than 10% of the body surface by the lesions. Exclusion criteria are:Extensive involvement of the skin ; topical or systemic antifungal therapy; and use of steroid or antibiotic within the last month before starting the study;pregnancy or likelihood of pregnancy; lactation and the patients who are not cooperative

Age

From **14 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

KURDISTAN University of Medical Sciences

Street address

KURDISTAN University of Medical Sciences

City

SANANDAJ

Postal code

6617711446

Approval date

2011-03-19, 1389/12/28

Ethics committee reference number

14/1203 28/12/1389

Health conditions studied

1

Description of health condition studied

versicolor

ICD-10 code

B36.0

ICD-10 code description

Pityriasis versicolor

Primary outcomes

1

Description

PTRIASIS versicolor

Timepoint

After completion of the treatment course the patients will be requested to refer for follow up after 1 weeks, one month and two months of treatment or in case of recurrence of the lesions.

Method of measurement

Skin smears are taken by a scalpel or a tape and will be examined by a pathologist for the presence of mycelium.

The patients with positive smears will enter into the study.

Secondary outcomes

1

Description

LOCAL complications

Timepoint

after 2 weeks, one month and two months of treatment

Method of measurement

by a physician or patient self-report

Intervention groups

1

Description

CONTROL: ketoconazol 2% cream .the creams are used topically twice a day for 2 weeks.

Category

Treatment - Drugs

2

Description

INTERVENTIONAL:terbinafin hydrochloride 1% cream.the creams are used topically twice a day for 2 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Doctor's office . BESATHOSPITAL

Full name of responsible person

DR.FAROKH RAD

Street address

KURDISTAN University of Medical Sciences

City

SANANDAJ

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

KURDISTAN University of Medical Sciences

Full name of responsible person

MOZHDEH ZAREI

Street address

KURDISTAN University of Medical Sciences

City

SANANDAJ

Grant name

Grant code / Reference number

25000000 R

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

KURDISTAN 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

MEDICAL UNIVERSITY OF KURDISTAN

Full name of responsible person

DR FAROKH RAD

Position

dermatologist

Other areas of specialty/work

Street address

KURDISTAN University of Medical Sciences

City

SANANDAJ

Postal code

6617711446

Phone

+98 87 1613 1278

Fax

+98 87 1666 5354

Email

MOZH.ZAREI@MUK.AC.IR

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

KURDISTAN University of Medical Sciences

Full name of responsible person

DR Farokh Rad

Position

dermatologist

Other areas of specialty/work

Street address

KURDISTAN province, Sanandaj, PASDARAN avenue,
KURDISTAN University of Medical Sciences

City

SANANDAJ

Postal code

6617711446

Phone

+98 87 1613 1278

Fax

+98 87 1666 5354

Email

mozh.zarei@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Medical University OF KURDISTAN

Full name of responsible person

DR Farokh Rad

Position

dermatologist

Other areas of specialty/work

Street address

KURDISTAN University of Medical Sciences

City

Sanandaj

Postal code

6617711446

Phone

+98 87 1613 1278

Fax

+98 87 1666 5354

Email

MZH.ZAREI@MUK.AC.IR

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