Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 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 wile 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
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Iran (Islamic Republic of)
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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
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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

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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