Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A survey in effectiveness of ketoconazole versus climbazole shampoo in the treatment of tinea versicolor .

Protocol summary

Study aim
A survay in effectiveness of ketoconazole shampoo versus climbazole shampoo in treatment of tinea versicolor

Design
The study is a single_blind , randomized clinical trial with control group and parallel group design.

Settings and conduct
This is a randomized single_blind clinical trial study.sixty patients with tinea versicolor and limited skin involvement over 12 years old of both sexes,attending Afzalipour hospital in Kerman enrolled the study. Patients were allocated to 2 groups (intervention and control) .intervention group will receive climbazole 2% shampoo and the control group will receive ketokonazole 2% shampoo.

Participants/Inclusion and exclusion criteria
"Inclusion criteria:" All patients with tinea versicolor with limited skin involvement that dose not require systemic treatment."Exclusion criteria": history of systemic underlying disease, history of allergy to climbazole, Pregnancy or lactation and Taking any topical or systemic anti fungal drug since the onset of the disease.

Intervention groups
Patients in control group were received Ketokonazole 2% shampoo "Iran Najo Company " (three days a week for three weeks and stay on the body ten minutes for foam shampoo) and in intervention group climbazole 2% shampoo "Asaderm Company" (three days a week for three weeks and stay on the body ten minutes for foam shampoo),respectively.

Main outcome variables
Fluorescence of lesions with Woods lamp , Mycological smear KOH of lesions.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190811044510N1**
Registration date: **2019-11-07, 1398/08/16**
Registration timing: **retrospective**

Last update: **2019-11-07, 1398/08/16**
Update count: **0**

Registration date
2019-11-07, 1398/08/16

Registrant information

Name
ziba omidvand

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3132 8236

Email address
z.omidvand@kmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2019-10-23, 1398/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A survey in effectiveness of ketoconazole versus climbazole shampoo in the treatment of tinea versicolor .

Public title

Evaluation of the effectiveness of climbazole shampoo treatment.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with tinea versicolor Limited skin disease that does not require systemic treatment

Exclusion criteria:

Underlying systemic disease Pregnancy and lactation Taking any topical or systemic antifungal drug since the onset of the disease history of allergy to climbazole

Age

From **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

For each person, a random number is selected from random number table with the help of mini tab16 software. If the number was odd, person falls into group A, and if the number was Even, person falls into group B.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patient are assigned to two groups A and B,randomly,and researcher who visits and evaluates patients and Also,the person who analyzes the data is not aware of these codes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences.

Street address

University of Medical Science Paradist , The begining of the axisof the seven Alavi garden.

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2018-12-25, 1397/10/04

Ethics committee reference number

]IR.KMU.AH.REC.1397.107

Health conditions studied

1

Description of health condition studied

tinea versicolor

ICD-10 code

B36.0

ICD-10 code description

Pityriasis versicolor

Primary outcomes

1

Description

fluorescence of lesion

Timepoint

At the beginning of the study (before intervention) ,4 weeks and 12 weeks after intervention.

Method of measurement

wood lamp

2

Description

effectiveness based on mycological smear KOH

Timepoint

At the beginning of the study (before intervention) ,4 weeks and 12 weeks after intervention.

Method of measurement

Lab evaluation of KOH smear

Secondary outcomes

1

Description

Patients symptoms(example :itching ,color variation and scaling)

Timepoint

At the beginning of the study (before intervention), 4 weeks and 12 weeks after intervention.

Method of measurement

Clinical examination through observation

Intervention groups

1

Description

Intervention group: patients are treated with shampoo climbazole 2%(Asaderm company)for 3 weeks ,3 days a week and do not wash the foam for 10 minutes.

Category

Treatment - Drugs

2

Description

Control group: Intervention group: patients are treated with shampoo ketoconazole 2%(iran najo company)for 3 weeks ,3 days a week and do not wash the foam for 10 minutes

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Afzalipour Hospital.

Full name of responsible person

Ziba Omidvand

Street address

Afzali Hospital,Emam Highway.

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7616913911

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z.omidvand@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

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Ebne sina Avenue,Jehad Blvd

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Kerman

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7619613159

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abpardakhty@kmu.ac.ir

Grant name

Annually grant

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Ziba Omidvand

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Afzali Hospital ,Emam Highway

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Rezvan Amiri

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Street address

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r_amiri@kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Ziba Omidvand

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available