

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

comparing effectiveness of niosomal ketoconazole cream versus niosomal climbazole cream in treatment of tinea versicolor patient

Protocol summary

Study aim

comparing efficacy of niosomal climbazole cream and niosomal ketoconazole cream in treatment of tinea versicolor

Design

two arms, parallel groups, randomized controlled, triple blind clinical trial

Settings and conduct

The study will be done on 40 patients visited at Afzalipour hospital. patient will be randomly allocated into two arms and will receive niosomal climbazole cream and niosomal ketoconazole cream twice daily for 3 weeks.

Participants/Inclusion and exclusion criteria

inclusion criteria: patient at least 12 years old
Exclusion criteria: patient with another cutaneous or systemic disease, history of hypersensitivity to ketoconazole or climbazole, using topical or systemic antifungal and corticosteroides drug in the previous 4 weeks, using other antifungal shampoo (selenium sulfide, pyrithine zinc), pregnancy, breastfeeding

Intervention groups

Intervention group: niosomal climbazole cream twice daily for 3 weeks. control group: niosomal ketoconazole cream twice daily for 3 weeks.

Main outcome variables

severity of tinea versicolor lesion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200725048196N1**

Registration date: **2021-05-02, 1400/02/12**

Registration timing: **prospective**

Last update: **2021-05-02, 1400/02/12**

Update count: **0**

Registration date

2021-05-02, 1400/02/12

Registrant information

Name

Fateme Rostami nasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4321 0043

Email address

frn1368@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-11-06, 1400/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparing effectiveness of niosomal ketoconazole cream versus niosomal climbazole cream in treatment of tinea versicolor patient

Public title

Assessing effectiveness of niosomal ketoconazol cream versus niosomal climbazol cream in tinea versicolor patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

A diagnosis of tinea versicolor made by the attending dermatologist who first visit patient at Afzalipour hospitals dermatology clinic Filling out and signing the written informed consent form by the patient patients age at least 12 years old Male or nonpregnant and nonbreastfeeding female

Exclusion criteria:

Any dermatologic or systemic disorders History of hypersensitivity to ketoconazole or clotrimazole Using systemic or topical antifungal drugs or corticosteroids during the 4weeks prior immediately before starting the trial Using other antifungal shampoo(selenium sulfide,pyrithione zinc) pregnancy or breastfeeding

Age

From **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

using table of random numbers,20patients will be allocated to each of the intervention and control groups. each patient will be given a number from 1 to 40.one row and one column will be randomly chosen from the table of random number.the intersection between this row and column will be the starting point of sampling.a finger will be put on the starting point and will be moved downwards through the table .the moving of the finger will be repeated until 20 participants of intervention group will be chosen.duplicate numbers and numbers larger than 40 will not be considered.the remaining 20 participants will be automatically put in the control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

letters A or B (niosomal clotrimazole cream and niosomal ketoconazole cream)will be allocated to each treatment arm .the only person aware of what treatment is specified to each of the groups will be the operator who responsible for handling in the treatment to the patients. patients,physicians and the analyzer of the final data will not be aware of the content of group A and B.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Kerman University of Medical sciences

Street address

Kerman University of Medical Science, Medical university campus, Haftbagh highway ,Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2021-01-31, 1399/11/12

Ethics committee reference number

IR.KMU.AH.REC.1399.076

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

Tinea versicolor lesion severity

Timepoint

At base line and 4,12 weeks later

Method of measurement

severity of lesion(scalling,pruritus,erythema,hyperpigmentation ,hypopigmentation)

Secondary outcomes

1

Description

treatment side effect

Timepoint

throughout study periode and up to 3months after the start of the study

Method of measurement

history taking and physical exam

Intervention groups

1

Description

Intervention group: will receive topical niosomal climbazol cream 0.5% (will be made by pharmacy research center of Kerman university of Medical Science) to be used twice daily for 3 weeks.

Category

Treatment - Drugs

2

Description

Control group: will receive niosomal ketoconazole cream 2% (will be made by pharmacy research center of Kerman university of Medical Science) to be used twice daily for 3 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzali pour Hospital dermatology clinic

Full name of responsible person

Rezvan Amiri

Street address

Afzalipour hospital, Imam Khomeini Highway

City

Kerman

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Kerman

Postal code

7616913911

Phone

+98 34 3132 8000

Email

rezvanamiri1358@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

Ebne sina Avenue, Jihad Blvd

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7619813159

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+98 34 3226 3855

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abpardakhti@kmu.ac.ir

Grant name

Grant code / Reference number

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

No

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

Rezvan Amiri

Position

Assistant professor of dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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rezvanamiri1358@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Fateme Rostami nasab

Position

Dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Fateme Rostami nasab
Position
Dermatology resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Afzalipour hospital, Imam highway
City

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