Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 40patients 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 3weeks.

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 4weeks,using og other antifungal shampoo(selenium sulfide,pyrithine zink),pregnancy,breastfeeding

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

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 climbazole Using systemic or topical antifungal drugs or crticosteroides during the 4weeks perior immediatly before starting the trial Using other antifungal shampoo(selenium sulfide,pyrithione zink) 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 parcipitants of intervention group will be chosen.duplicate numbers and numbers larger than 40 will not be considered.the remaining 20 parcipitants will be automatically put in the control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

letters A or B (niosomal climbazole 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 recive topical niosomal climbazol cream0.5%(will be made by pharmacy research center of Kerman university of Medical Science) to be used twice daily for 3weeks.
Category
Treatment - Drugs

2

Description
Control group: will recive niosomal ketoconazole cream2% (will be made by pharmacy research center of Kerman university of Medical Science)to be used twice daily for 3weeks.
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
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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,Jahad Blvd
City
Kerman
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7619813159
Phone
+98 34 3226 3855
Email
abpardakhty@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
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Person responsible for updating data

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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