# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

31 May 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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**Phone**
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**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,Jahad Blvd
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**Province**
Kerman
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**Phone**
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**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**
Dermatology
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## Person responsible for scientific inquiries

**Contact**
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**Position**
Dermatology resident
**Latest degree**
Medical doctor
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## Person responsible for updating data

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**Province**
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**Email**
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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