

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

##### Study aim

A survey 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 clotrimazole 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 clotrimazole

### **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 beginning 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**

JIR.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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**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,Jehad Blvd

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**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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**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**

Dermatology

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
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Ziba Omidvand  
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Resident  
**Latest degree**  
Medical doctor  
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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