

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Comparison of the Effect of Terbinafine alone with the Combination of Terbinafine and Prednisolone in the Treatment of Inflammatory Tinea Capitis

#### Protocol summary

Comparison of scar rate and treatment score in two groups

#### Study aim

1- Comparison of scarring in patients four months after treatment 2--Comparison of response score to treatment (anti-inflammatory effect) of patients two months after treatment

#### Design

Clinical trial with parallel groups, double-blind, randomized, on 40 patients.

#### Settings and conduct

In this interventional study, 40 patients referred to HajDai Dermatology Clinic who are clinically suspected to have inflammatory Tinea Capitis and are confirmed through paraclinical studies are included in the study. Patients are randomly divided into two groups receiving Terbinafine plus placebo and receiving Terbinafine plus Prednisolone as the first and second groups, respectively. Photos of patients are taken at the beginning, during and at the end of the treatment. Patients are followed up initially for up to 4 weeks, weekly and then monthly for up to 4 months in terms of recovery, hair regrowth and possible complications. Treatment results will be reviewed by an impartial dermatologist. Information and treatment results are recorded in patients' files and analyzed by appropriate statistical methods.

#### Participants/Inclusion and exclusion criteria

Patients with inflammatory tinea capitis whose diagnosis is confirmed clinically and by smear and culture are included in the study. Patients who have already received corticosteroids, patients with immune system deficiency, pregnancy, breastfeeding, diabetic patients are not included in the study.

#### Intervention groups

Patients will be randomly assigned to 2 groups (Terbinafine and placebo alone or Terbinafine and Prednisolone combination group) in equal numbers.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240225061105N1**

Registration date: **2024-03-04, 1402/12/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-03-04, 1402/12/14**

Update count: **0**

##### Registration date

2024-03-04, 1402/12/14

##### Registrant information

##### Name

Hossein Kavoussi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3835 6643

##### Email address

hkavoussi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-15, 1402/08/24

##### Expected recruitment end date

2024-11-14, 1403/08/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the Effect of Terbinafine alone with the Combination of Terbinafine and Prednisolone in the Treatment of Inflammatory Tinea Capitis

**Public title**  
Comparison of the Effect of Terbinafine alone with the Combination of Terbinafine and Prednisolone in the Treatment of Inflammatory Tinea Capitis

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
All Patients with Inflammatory Tinea Capitis that have been confirmed Clinically and by Smear and Culture.  
**Exclusion criteria:**  
Patients who have Previously received Corticosteroids  
Patients with Immune System Deficiency  
Pregnancy  
Breastfeeding  
Diabetic patient

**Age**  
No age limit

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this interventional study, patients referred to Hajdaiee dermatology clinic who are clinically suspected of inflammatory tinea capitis and are confirmed through para-clinical assessment are included in the study. Patients are randomly assigned to two groups receiving Terbinafine plus placebo and receiving Terbinafine plus Prednisolone, as first and second groups, respectively. Blocks of 4 (10 blocks) will be produced by the software by the statistical consultant. The registration of people is done by the dermatology assistant. People are assigned to two groups by the secretary of the group. The follow-up of the treatment results is done by a dermatologist who does not know about the allocation of people. The concealment mechanism is done by placing the blocks in the sealed envelopes, which is at the disposal of the secretary. Photo of the patients is taken at the beginning, during and at the end of the treatment. Patients are followed up initially weekly for up to 4 weeks, then monthly for up to 4 months in terms of improvement, hair regrowth and possible complications. Treatment outcome will be reviewed by an independent dermatologist. Information and treatment results are recorded in patients' files and analyzed by appropriate statistical methods.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The Patient and the Data Assessor (A Dermatologist who does not know the Allocation of Subjects) are blinded.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

##### Street address

No. 57, Agha Razi Alley, Golestan Crossroads, Kermanshah

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6714763655

#### Approval date

2023-11-14, 1402/08/23

#### Ethics committee reference number

IR.KUMS.MED.REC.1402.244

## Health conditions studied

### 1

#### Description of health condition studied

Inflammatory Tinea Capitis

#### ICD-10 code

#### ICD-10 code description

### 2

#### Description of health condition studied

Kerion

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

scar rate

#### Timepoint

Before treatment and four months after treatment

#### Method of measurement

photo

## 2

### Description

اسکور پاسخ به درمان ضد التهابی

### Timepoint

Before treatment and 2 months after treatment

### Method of measurement

Questionnaire: Based on the clinical symptoms of redness, edema, pustule, scaling, itching, pain and hair loss, it will be scored. Scoring will be done from a minimum score of 0 to a maximum score of 7.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First Intervention group: This group receives Terbinafine plus placebo. Based on the patient's weight, less than 25 kilograms 125 mg, between 25-45 kilograms 187.5 mg, and more than 45 kilograms 250 mg will be prescribed oral Terbinafine tablets (Binafine, Tehran Chemical Company) for four weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: This group receives combined treatment of Terbinafine and Prednisolone. Based on the patient's weight, less than 25 kilograms 125 mg, between 25-45 kilograms 187.5 mg, and more than 45 kilograms 250 mg will be prescribed oral Terbinafine tablets (Binafine, Tehran Chemical Company) for four weeks. For Prednisolone, for less than 10 years, 2.5 mg and for more than 10 years, 5 mg will be prescribed for 4 weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Haj Dayi Kermanshah Skin Specialist Clinic

##### Full name of responsible person

Hosein Kavousi

##### Street address

Haj Dai Skin Clinic , Golestan Crossroads ,  
Kermanshah

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6714653113

##### Phone

+98 83 3845 3486

##### Fax

##### Email

soheilaazmoodeh88@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

siroos jalili

##### Street address

Kermanshah University of Medical Sciences , Shahid  
Beheshti Boulevard , Kermanshah

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

##### Phone

+98 83 3839 5885

##### Email

info@kums.ac.ir

##### Web page address

http://www.kums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

##### Full name of responsible person

Soheila Azmoodeh

##### Position

Dermatology assitant

##### Latest degree

Medical doctor  
**Other areas of specialty/work**  
Dermatology  
**Street address**  
Haj Dayi Clinic , Golestan Crossroads , Kermanshah  
**City**  
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**Province**  
Kermanshah  
**Postal code**  
6714653113  
**Phone**  
+98 11 3463 3338  
**Email**  
soheilaazmoodeh88@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Hosein.Kavoussi  
**Position**  
professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dermatology  
**Street address**  
Haj Dai skin specialist clinic , Golestan intersection ,  
Kermanshah  
**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6714653113  
**Phone**  
+98 83 3845 3486  
**Email**  
hkavoussi@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Soheila Azmoodeh  
**Position**  
Dermatology assitant  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**

Dermatology  
**Street address**  
Haj Dayi Clinic , Golestan Crossroads , Kermanshah  
**City**  
Kermanshah  
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Kermanshah  
**Postal code**  
6714653113  
**Phone**  
+98 11 3463 3338  
**Email**  
soheilaazmoodeh88@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Information about the main outcome can be shared after de-identifying individuals.

### When the data will become available and for how long

Immediately after printing the results.

### To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

### Under which criteria data/document could be used

Analysis on data related to age, sex, location of lesion and occupation of patients is allowed for retrospective studies.

### From where data/document is obtainable

Dr. Soheila Azmoodeh, Dermatology Resident, Kermanshah University of Medical Sciences, Haj Daei Dermatology Clinic: Golestan Crossroad, Kermanshah, soheilaazmoodeh88@gmail.com 00989113582535 Dr. Hossein Kavousi, Dermatologist, Kermanshah University of Medical Sciences, Haj Dai Dermatology Clinic: Kermanshah, Golestan Crossroads, hkavousi@gmail.com 00989181322243

### What processes are involved for a request to access data/document

The requester can request to receive data through email. It will receive the data after 2 days.

### Comments