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 Tina Capitis

Protocol summary

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

Comparison of scar rate and treatment score in two groups

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

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Email address

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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 Tina Capitis

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All Patients with Inflammtory Tinea Capitis that have been confirmed Clinically and by Smear and Culture.

Exclusion criteria:

Patients who have Previosly recieved Corticosteroids Patients with Immune System Deficiency Pregnancy Breastfeding 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 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
siroos jalili
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Phone
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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

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Latest degree

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Person responsible for updating data

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Name of organization / entity

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Email

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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