

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effect of isotretinoin along with itraconazole in the treatment of patients with dermatophytes

Protocol summary

Study aim

Main objective: Investigating the effect of retinoid drug called isotretinoin along with azole subgroup drug called itraconazole in the treatment of patients diagnosed with skin fungus Secondary objective: Investigating the effect of isotretinoin along with itraconazole in the treatment of patients with skin fungus in relation to age / gender / the duration of the onset of the disease Investigating the effect of isotretinoin along with itraconazole in the treatment of patients with skin fungus according to the size of the lesions and the location of the lesion

Design

The clinical trial has a control group, a blinded, randomized, phase 3 on 80 patients. The random allocation of patients is done through the block randomization method, and a table of random numbers is used to prepare a random list

Settings and conduct

Patients are evaluated before the intervention, 1 month later, 2 months later, 3 months later and one month after the end of the intervention based on the criteria stated by the specialist.

Participants/Inclusion and exclusion criteria

80 patients diagnosed with dermatophyte by KOH test (potassium hydroxide, the solution in the test) will be included in the study after obtaining informed consent People with immune deficiency and people with kidney and liver problems, diabetes, history of alcohol consumption, less than 12 and more than 60 years old, and pregnant and lactating women will be excluded from the study

Intervention groups

Patients will be randomly divided into two groups of 40 people The control group (which will receive itraconazole at a dose of 200 mg daily) and the experimental group will be treated with a combination of itraconazole (at a dose of 100 mg twice a day) and isotretinoin (at a dose of 20 mg once a day)

Main outcome variables

Response to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240527061914N1**

Registration date: **2025-02-13, 1403/11/25**

Registration timing: **registered_while_recruiting**

Last update: **2025-02-13, 1403/11/25**

Update count: **0**

Registration date

2025-02-13, 1403/11/25

Registrant information

Name

Sara Masoomi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3324 8863

Email address

saramasoomi1376@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-12, 1403/09/22

Expected recruitment end date

2025-08-12, 1404/05/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Investigating the effect of isotretinoin along with itraconazole in the treatment of patients with dermatophytes
Public title	Investigating the effect of isotretinoin along with itraconazole in the treatment of skin fungus
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Patients who have been diagnosed with dermatophyte by Koh test
Exclusion criteria:	Under 12 years Over 60 years old pregnant milked Has a history of diabetes Has a history of liver disease Has a history of kidney disease History of alcohol consumption
Age	From 12 years old to 60 years old
Gender	Both
Phase	3
Groups that have been masked	Participant
Sample size	Target sample size: 80
Randomization (investigator's opinion)	Randomized
Randomization description	block randomization The table of random numbers is used in such a way that a random number is generated at each stage. If the generated number is between 0 and 4, the patient is placed in the Isotretinoin and Itraconazole group, and if the number is between 5 and 9, the patient is placed in the Itraconazole group. Therefore, we repeat this process many times until eligible patients enter the study.
Blinding (investigator's opinion)	Single blinded
Blinding description	Two groups of 40 people with dermatophytes are randomly treated with antifungal. The method of blinding is single blind, which means that the patient does not know the type of treatment (before starting the treatment, the patients will be ethically discussed and they will enter the study with full consent and knowledge).
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Fatemeh Saeidi
Street address	Keshavarz Blvd., Intersection of Qods St., Central Building of Tehran University of Medical Sciences
City	Tehran
Province	Tehran
Postal code	1417863181
Approval date	2024-10-28, 1403/08/07
Ethics committee reference number	IR.TUMS.IKHC.REC.1403.328
Health conditions studied	
1	
Description of health condition studied	Dermatophyte (fungal disease)
ICD-10 code	B35.4
ICD-10 code description	Tinea corporis
Primary outcomes	
1	
Description	Comparison of the effect of isotretinoin on the treatment of dermatophytes
Timepoint	Examination at the beginning of the study and then monthly until the dermatophyte infection is completely resolved
Method of measurement	Clinical examination
Secondary outcomes	empty
Intervention groups	
1	
Description	Intervention group: treated with itraconazole 100 mg every 12 hours and isotretinoin 20 mg every other day and sertaconazole ointment every 8 hours and shampoo ketoconazole 3 times a week
Category	Treatment - Drugs

2

Description

Control group: treated with itraconazole 100 mg every 12 hours and sertaconazole ointment every 8 hours and shampoo ketoconazole 3 times a week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Hajar Masoomi Farahabadi

Street address

Vahdat eslami street

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Tehran

Postal code

1199663911

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saramasoomi1376@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Ali Akbari Sari

Street address

Tehran - Vahdat Eslami St. - Razi Hospital

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Hajar Masoomi Farah abadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Vesal Shirazi Street - between Italy Street and Parisi

Ancient Alley - Vesal Hostel

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. safoura shakoei nezhad

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Hajar Massomi Farahabadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Vesal Shirazi - between Italy Street and the ancient alley of Parisi - Vesal dormitory

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The data will be provided to other researchers upon request

When the data will become available and for how long

It can be used after completing the study and statistical analysis and after the article is published

To whom data/document is available

researchers

Under which criteria data/document could be used

It can be used after the study and statistical analysis is completed and after the article is published

From where data/document is obtainable

Mrs. Dr. Saffora Shekoi Nejad Mrs. Dr. Hajar Masoumi Mr. Dr. Taha Shahbazi Mr. Dr. Alireza Banani

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

Questions will be answered by email

Comments