Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr.Ali Akbari Sari
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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
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Person responsible for updating data

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Position
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Other areas of specialty/work
Dermatology

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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