

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Efficacy of oral voriconazole versus oral itraconazole in the treatment of dermatophyte infections

Protocol summary

Study aim

In this study, we aim to measure the efficacy oral voriconazole versus oral itraconazole in the treatment of dermatophyte infections.

Design

A randomized clinical trial with two parallel intervention groups; double-blind; phase 3; on 76 patients.

Settings and conduct

Dermatology department, PNS Shifa hospital, Karachi

Participants/Inclusion and exclusion criteria

Inclusion criteria: chronic and recurrent dermatophyte infections. Exclusion criteria: age less than 15 and greater than 90 years, hyperlipidemia, abnormal renal and liver function tests, tinea capitis and unguum, pregnant and breastfeeding women.

Intervention groups

In Group A the patients were treated with oral voriconazole 200mg twice daily In group B the patients were treated with oral itraconazole 100mg twice daily Treatment given for four weeks or less in patients in which complete response is achieved.

Main outcome variables

Treatment of dermatophyte infections based on clinical response and microscopic findings using KOH solution

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210823052264N3**

Registration date: **2023-05-19, 1402/02/29**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-19, 1402/02/29**

Update count: **0**

Registration date

2023-05-19, 1402/02/29

Registrant information

Name

Najia Ahmed

Name of organization / entity

PNS shifa

Country

Pakistan

Phone

+92 81 2864092

Email address

najiaomer@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-25, 1402/02/05

Expected recruitment end date

2023-10-25, 1402/08/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of oral voriconazole versus oral itraconazole in the treatment of dermatophyte infections

Public title

Efficacy of oral voriconazole versus itraconazole in the treatment of dermatophyte infections

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic and recurrent dermatophyte infections (chronic refers to infections present for over 6 months, recurrent refers to patients with an infection in which symptoms reappear in 6 weeks after complete cure or stopping of

treatment).

Exclusion criteria:

Patients with age less than 15 and greater than 90 years, Hyperlipidemia, Abnormal liver and renal function tests, Pregnant and breast feeding females.

Age

From **15 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization done by lottery method, in which small chits of paper are kept in a jar and the patients will be asked to pick one deciding their treatment regimen.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participant, the investigator and outcome assessor were all blinded except for one physician who was supposed to recruit the patients in the group. As explained above the participants will be asked to pick up a chit of paper from a jar that will decide in which group they will fall into. The participants will not open the chit themselves, but will hand it over to the non blinded assessor, who will give them the medicine without any label showing the brand or generic name.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical review committee, PNS Shifa

Street address

PNS Shifa Hospital, DHA Phase 2, Karachi

City

Karachi

Postal code

75500

Approval date

2023-04-27, 1402/02/07

Ethics committee reference number

ERC/2023/DERMA/14

Health conditions studied**1****Description of health condition studied**

Dermatophyte infection

ICD-10 code

B35

ICD-10 code description

Dermatophytosis

Primary outcomes**1****Description**

Clinical response based on clearance of lesion and absence of fungal hyphae on KOH microscopy

Timepoint

Patients were evaluated clinically on 7th and 14th day of treatment and 4 weeks after completion of treatment.

Method of measurement

Clinical evaluation

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In group "A" patients were treated with Tab Voriconazole 200mg twice a day for four weeks or less in patients in which clinical response is achieved

Category

Treatment - Drugs

2**Description**

Intervention group: In group "B" patients were treated with Tab Itraconazole 100mg twice daily for four weeks or less in which clinical response is achieved

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

PNS Shifa Hospital

Full name of responsible person

Dr Maira Ali

Street address

Main Korangi Rd, Near Kala Pul, DHA Phase 2, Clifton,

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Sponsors / Funding sources

1

Sponsor

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Fax
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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
PNS SHIFA
Proportion provided by this source
100
Public or private sector
Private
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
PNS Shifa
Full name of responsible person
Dr Maira Ali
Position
Resident
Latest degree

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Person responsible for updating data

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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

Primary outcome

When the data will become available and for how long

1 month after the trial and for lifetime

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Many

From where data/document is obtainable

mairasmuian2012gmail.com

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

Request

Comments