# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 assesor 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 accessor, 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**

Ehical 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 clearence 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" patietns 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 100md 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,

Karachi

**City**
Karachi

**Postal code**
74900

**Phone**
+92 332 3676671

**Fax**
+92 21 48506592

**Email**
mairasmuian2012@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
PNS SHIFA

**Full name of responsible person**
Dr Maira Ali

**Street address**
Main Korangi Rd, nea Kala Pul, Clifton, Karachi

**City**
Karachi

**Postal code**
74900

**Phone**
+92 21 48506592

**Fax**
+92 21 48506592

**Email**
mairasmuian2012@gmail.com

**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**
Medical doctor

**Other areas of specialty/work**
Dermatology

**Street address**
Dr Maira Ali, 5th Floor, OPD Tower, PNS Shifa Hospital

**City**
Karachi

**Province**
Sindh

**Postal code**
74900

**Phone**
+92 21 48506592

**Fax**

**Email**
mairasmuian2012@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
PNS SHIFA

**Full name of responsible person**
Dr Maira Ali

**Position**
Resident

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Dermatology

**Street address**
Dr Maira Ali, 5th Floor, OPD Tower, PNS Shifa Hospital

**City**
Karachi

**Province**
Sindh

**Postal code**
74900

**Phone**
+92 21 48506592

**Email**
mairasmuian2012@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
PNS SHIFA

**Full name of responsible person**
Dr Maira Ali

**Position**
Resident

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Dermatology

**Street address**
Dr Maira Ali, 5th Floor, OPD

**City**
Karachi

**Province**

Sindh

**Postal code**

74900

**Phone**

+92 21 48506592

**Email**

mairasmuian2012@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**

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**