

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy of oral itraconazole with sertaconazole cream versus oral itraconazole with clotrimazole cream in dermatophytosis - a randomized controlled trial in a tertiary care hospital in Pakistan

#### Protocol summary

##### Study aim

In this study, we aim to measure the efficacy of oral itraconazole with sertaconazole cream versus oral itraconazole with clotrimazole cream in dermatophytosis

##### Design

A randomized controlled trial with two parallel intervention groups; double-blind; phase 3; on 118 patients.

##### Settings and conduct

Dermatology Department, PNS Shifa Hospital, Karachi

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients of both, male and female genders, in age group 12-75 years with clinical manifestations of cutaneous dermatophyte infections (tinea corporis/tinea cruris/tinea faciei) and confirmation done with skin scraping positive for potassium hydroxide (KOH) mount. Exclusion criteria: Patients with age less than 12 years and greater than 75 years. Hyperlipidemia Abnormal liver function tests Pregnant and breast feeding females. solitary lesion which is less than 3 cm in diameter hypersensitivity to antifungals if patients are on any systemic medications known to have interactions with itraconazole superadded bacterial infections patients on immunosuppressive drugs patients who are known case of liver or renal disease Tinea capitis and onychomycosis

##### Intervention groups

In Group A the patients were treated with oral itraconazole 100mg twice daily with topical sertaconazole cream. In Group B, the patients were treated with oral itraconazole 100mg twice daily with topical clotrimazole cream. 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: **IRCT20230531058353N1**

Registration date: **2023-08-07, 1402/05/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-08-07, 1402/05/16**

Update count: **0**

##### Registration date

2023-08-07, 1402/05/16

##### Registrant information

##### Name

Absha Abbasi

##### Name of organization / entity

PNS Shifa Hospital

##### Country

Pakistan

##### Phone

+92 21 48506482

##### Email address

abshaabbasi5@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-26, 1402/04/05

##### Expected recruitment end date

2023-12-26, 1402/10/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Efficacy of oral itraconazole with sertaconazole cream versus oral itraconazole with clotrimazole cream in dermatophytosis - a randomized controlled trial in a tertiary care hospital in Pakistan

### Public title

Efficacy of oral itraconazole with sertaconazole cream versus oral itraconazole with clotrimazole cream in dermatophytosis - a randomized controlled trial in a tertiary care hospital in Pakistan

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients of both, male and female genders, in age group 12-75 years with clinical manifestations of cutaneous dermatophyte infections (tinea corporis/tinea cruris/tinea faciei) and confirmation done with skin scraping positive for potassium hydroxide (KOH) mount.

#### Exclusion criteria:

Patients with age less than 12 years and greater than 75 years. Hyperlipidemia Abnormal liver function tests Pregnant and breast feeding females. solitary lesion which is less than 3 cm in diameter hypersensitivity to antifungals if patients are on any systemic medications known to have interactions with itraconazole superadded bacterial infections patients on immunosuppressive drugs patients who are known case of liver or renal disease Tinea capitis and onychomycosis

### Age

From **12 years** old to **75 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Investigator
- Outcome assessor

### Sample size

Target sample size: **118**

### 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. Half of the chits will be Group A and half of the chits will be Group B. Chits will be folded uniformly to conceal their identity.

### 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 be

decide in which group they will fall into. Half of the chits will be Group A and half of the chits will be Group B. The chits will be folded uniformly to conceal identity. 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, Pakistan

##### City

Karachi

##### Postal code

75500

#### Approval date

2023-06-27, 1402/04/06

#### Ethics committee reference number

ERC/2023/DERM/30

## 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 evaluation and absence of fungal hyphae on KOH microscopy.

#### Timepoint

Patients were evaluated clinically on 2 weeks of treatment then 4 weeks of treatment (end point) and then further followed up after 4 weeks.

#### Method of measurement

Clinical evaluation

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: In group "A", patients were treated with Tab Itraconazole 100mg twice a day and sertaconazole cream applied topically twice a day for 4 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 100 mg twice a day and clotrimazole cream applied twice a day for 4 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 Absha Abbasi

#### Street address

Main Korangi Rd, near Kala Pul, DHA Phase 2, Clifton, Karachi

#### City

Karachi

#### Postal code

74900

#### Phone

+92 334 2650223

#### Email

abshaabbasi5@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

PNS Shifa

#### Full name of responsible person

Dr Absha Abbasi

#### Street address

Main Korangi Rd, near Kala Pul, Clifton, Karachi, Sindh, Pakistan

#### City

Karachi

#### Postal code

74900

#### Phone

+92 21 48506592

#### Email

abshaabbasi5@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 Absha Abbasi

#### Position

Resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Dermatology

#### Street address

Dr Absha Abbasi, 5th floor, OPD Tower, PNS Shifa Hospital

#### City

Karachi

#### Province

Sindh

#### Postal code

74900

#### Phone

+92 21 48506592

#### Email

abshaabbasi5@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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

PNS Shifa

**Full name of responsible person**

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**Position**

Resident

**Latest degree**

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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**

abshaabbasi5@gmail.com

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

Request

**Comments**