

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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

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74900

Phone

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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

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Full name of responsible person

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Position

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

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Full name of responsible person

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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