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 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
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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 Absha Abbasi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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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
abshaabbasi5@gmail.com
What processes are involved for a request to access data/document
Request
Comments