# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Jun 2026

## Comparison Of Oral Terbinafine Alone And Oral Terbinafine With Fluconazole in Dermatophytosis Among Children

### Protocol summary

**Study aim**

To compare the efficacy of oral terbinafine alone and oral terbinafine and fluconazole in treating dermatophytes among children under 18 years.

**Design**

Randomized controlled trail of 200 patients, single centered study

**Settings and conduct**

Study would be conducted in Dermatology department, PNS Shifa Hospital, Karachi.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: (a) clinical diagnosis of tinea corporis, tinea cruris or tinea faciei, Tinea pedis, tinea capitis (b) microscopic confirmation (potassium hydroxide [KOH] microscopy), (c) age birth to 18 years and (d) no treatment with terbinafine or fluconazole in last one month. Exclusion criteria (a) presence of any other type(s) of tinea, e.g., onychomycosis, b) inability to come for follow-up, c) history of adverse reaction to terbinafine and/or fluconazole, D) history of renal, liver or cardiac disease

**Intervention groups**

Patients would be divided into 2 groups by lottery method based on treatment regimens as follows: 1. Group A: Terbinafine orally at following doses: 62.5 mg/day for <10 kg body weight, 125 mg/day for 10-20 kg body weight, and 250 mg/day for >20kg body weight. 2. Group B: Terbinafine orally at following doses: 62.5 mg/day for <20 kg body weight, 125 mg/day for 20–40 kg body weight, and 250 mg/day for >40 kg body weight. And fluconazole orally at 6mg/kg/every alternate day

**Main outcome variables**

Outcome measures and statistical analysis: Patients were labeled as the following at both fourth and eighth weeks. Complete response: Cured (complete clinical resolution of all lesions) Partial response: Partially cured (more than 50% improvement in the total BSA) and No response: Increase in severity of the lesions or no improvement in the lesions after 4 weeks of starting antifungal agents RELAPSE: Reappearance of lesions once they have been cured on follow up visit,

### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20230428058014N1**
Registration date: **2023-05-26, 1402/03/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-26, 1402/03/05**
Update count: **0**

**Registration date**

2023-05-26, 1402/03/05

**Registrant information**

**Name**
Ammara Hameed
**Name of organization / entity**
Bahria University Medical and Dental College
**Country**
Pakistan
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**Email address**
ammara.bumdc@bahria.edu.pk

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-05-22, 1402/03/01

**Expected recruitment end date**

2023-11-22, 1402/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison Of Oral Terbinafine Alone And Oral Terbinafine With Fluconazole in Dermatophytosis Among Children

**Public title**

Treating dermatophytosis among children

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

clinical diagnosis of tinea corporis, tinea cruris or tinea faciei, Tinea pedis, tinea capitis microscopic confirmation (potassium hydroxide [KOH] microscopy) age birth to 18 years no treatment with terbinafine or fluconazole in last one month.

**Exclusion criteria:**

presence of any other type(s) of tinea, e.g., onychomycosis, inability to come for follow-up, history of adverse reaction to terbinafine and/or fluconazole, history of renal, liver or cardiac disease

**Age**

From **1 month** old to **18 years** old

**Gender**

Both

**Phase**

4

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **200**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Individuals are randomly divided into two groups on simple method based on sealed envelops. Each participant would be offered a sealed envelop, neither the participant nor the investigator would be aware of the drugs inside the sealed envelop.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The participant, principle investigator, outcome assessors and care givers will all be blinded except for one physician who will open the sealed envelope and give the patient drug A or drug B, as per the group code inside the envelope, without informing the patient if he is being given drug A or drugB

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Conducted at PNS Shifa Hospital

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of PNS Shifa Hospital, Karachi

**Street address**

Flat number 6 / 34 ,PHA Apartments,

**City**

Karachi

**Postal code**

77440

**Approval date**

2023-05-11, 1402/02/21

**Ethics committee reference number**

ERC/2023/Paeds Derma/15

## Health conditions studied

**1**

**Description of health condition studied**

Dermatophytosis- fungal infection

**ICD-10 code**

B35

**ICD-10 code description**

Dermatophytosis

## Primary outcomes

**1**

**Description**

Clinical Response based on clearance of lesions.

**Timepoint**

4 weeks , 8 weeks

**Method of measurement**

Clinical response evaluation

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

1. Intervention group A: in Group A the patients are treated with Terbinafine orally at following doses:62.5 mg/day for <10 kg body weight,125 mg/day for 10-20 kg body weight, and 250 mg/day for >20kg body weight.

**Category**

Treatment - Drugs

**2**

**Description**
Intervention group B: In Group B: Terbinafine orally at following doses:62.5 mg/day for <20 kg body weight,125 mg/day for 20–40 kg body weight, and 250 mg/day for >40 kg body weight. And fluconazole orally at 6mg/kg/every alternate day

**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
PNS Shifa Hospital, Karachi

**Full name of responsible person**
Ammara Hameed

**Street address**
Flat number 6 / 34 ,PHA Apartments, Gulistan-e-Jauhar

**City**
Karachi

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**Phone**
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ammarahameed@hotmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
PNS Shifa Hospital, Karachi

**Full name of responsible person**
Najia Omer

**Street address**
DHA Phase 2, Karachi

**City**
Karachi

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**Phone**
+92 332 5066303

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najiaomer@yahoo.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
PNS Shifa Hospital, Karachi

**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 Hospital, Karachi

**Full name of responsible person**
Ammara Hameed

**Position**
Assistant professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Dermatology

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## Person responsible for scientific inquiries

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Assistant Professor

**Latest degree**
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**
there is no further information

**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**
No - There is not a plan to make this available

**Clinical Study Report**
Not applicable

**Analytic Code**
Not applicable

**Data Dictionary**
Not applicable

**Title and more details about the data/document**
IPD collected for primary outcome

**When the data will become available and for how long**
after the study is published

**To whom data/document is available**
only available for people working in academic institutions.

**Under which criteria data/document could be used**
Not applicable

**From where data/document is obtainable**
The investigator

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

**Comments**