

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 trial 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

Phone

+92 21 32780931

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 envelopes. Each
participant would be offered a sealed envelope, neither
the participant nor the investigator would be aware of
the drugs inside the sealed envelope.

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 drug B

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

Postal code

77440

Phone

+92 333 3416393

Email

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

Postal code

77440

Phone

+92 332 5066303

Email

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

Street address

DHA Phase 2

City

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Province

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Postal code

77440

Phone

+92 333 3416393

Email

ammarahameed@hotmail.com

Person responsible for scientific 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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City

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Province

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Phone

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Person responsible for updating data

Contact

Name of organization / entity

PNS Shifa Hospital, Karachi

Full name of responsible person

Ammara Hameed

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Email

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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