Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
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 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

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
Karachi

Province
Sindh

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

Street address
DHA Phase 2

City
Karachi

Province
Sindh

Postal code
77440

Phone
+92 333 3416393

Email
ammarahameed@hotmail.com

Person responsible for updating data

Contact

Name of organization / entity
PNS Shifa Hospital, Karachi

Full name of responsible person
Ammara Hameed

Position
Assistant Professor

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Dermatology

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Province
Sindh

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77440

Phone
+92 333 3416393

Email
ammarahameed@hotmail.com

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