

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Efficacy oral Terbinafine alone and combined with 20% topical urea in the treatment of Pediatric Dermatophytosis and Prevention of Chronicity and Recurrence. A double-blind Randomized control trail.

#### Protocol summary

##### Study aim

To assess the efficacy of topical urea in combination with oral terbinafine for the treatment of childhood dermatophytosis

##### Design

Randomized control trial

##### Settings and conduct

Lady reading hospital, Department of pediatrics

##### Participants/Inclusion and exclusion criteria

inclusion criteria: patient with superficial dermatophytosis between age 2-14 years exclusion criteria:

##### Intervention groups

1. using terbinafine alone 2. using terbinafine along with topical urea

##### Main outcome variables

1. Clinical cure 2. prevention of chronicity and recurrence

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250131064579N1**

Registration date: **2025-03-09, 1403/12/19**

Registration timing: **prospective**

Last update: **2025-03-09, 1403/12/19**

Update count: **0**

##### Registration date

2025-03-09, 1403/12/19

##### Registrant information

##### Name

MUHAMMAD FAHIM

##### Name of organization / entity

Lady Readin Hospital Peshawar, KPK, Pakistan

##### Country

Pakistan

##### Phone

+92 346 5354921

##### Email address

muhammad.fahmeemyaseen@lrh.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-04-01, 1404/01/12

##### Expected recruitment end date

2025-09-01, 1404/06/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Efficacy oral Terbinafine alone and combined with 20% topical urea in the treatment of Pediatric Dermatophytosis and Prevention of Chronicity and Recurrence. A double-blind Randomized control trail.

##### Public title

keratolytics for dermatophytosis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

All patients with dermatophytes infection diagnosed on clinical grounds, between age 2-14 and willing to participate in the study.

##### Exclusion criteria:

Patients with history of any topical or systemic antifungals used for the current infection, patients with diabetes mellitus or any other immunosuppression or

having history of sensitivity to terbinafine or topical urea. Similarly, patients with past or current hepatitis or other liver diseases were considered ineligible for the trial. Finally patients with T.capitis and onychomycosis were not considered due to prolonged treatment regimes

### Age

From **2 years** old to **14 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Investigator

### Sample size

Target sample size: **140**

### Randomization (investigator's opinion)

Randomized

### Randomization description

simple randomization with individual patient as unit using technique of sealed envelopes

### Blinding (investigator's opinion)

Double blinded

### Blinding description

In this trial, participants would be randomly assigned to either group 1 (receiving the terbinafine) or group 2 (receiving topical urea with terbinafine). Both the participants and the clinical staff administering the medication or measuring outcomes would not know which group a participant is in. T

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Institutional review board, lady reading hospital

##### Street address

old city, near bala hisar fort

##### City

peshawar

##### Postal code

25100

#### Approval date

2024-09-04, 1403/06/14

#### Ethics committee reference number

328/LRH/MTI

## Health conditions studied

### 1

#### Description of health condition studied

Dermatophytosis

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Clinical improvement in skin lesions

#### Timepoint

Followup at weekly intervals and finally at 4th week

#### Method of measurement

By assessing the parameters like complete remission (disappearance of all lesions), chronic and recurrent cases in both groups

## Secondary outcomes

### 1

#### Description

chronicity and recurrence of dermatophytosis

#### Timepoint

4 weekly and then finally at 6 months

#### Method of measurement

clinical assessment of recurrent and chronic cases in both groups

## Intervention groups

### 1

#### Description

Intervention group:

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group:

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Lady reading hospital

##### Full name of responsible person

Dean, lady reading hospital

##### Street address

old city, Peshawar, near bala hisar fort

**City**  
peshawar  
**Postal code**  
25100  
**Phone**  
+92 91 9211430  
**Email**  
hr@lrh.gov.pk

**City**  
peshawar  
**Province**  
kpk  
**Postal code**  
25100  
**Phone**  
+92 302 8124881  
**Email**  
mr.aizazurrahman@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Lady reading hospital  
**Full name of responsible person**  
Dean  
**Street address**  
Old city,near bala hisar fort  
**City**  
Peshawar  
**Postal code**  
25100  
**Phone**  
+92 91 9211430  
**Email**  
hr@lrh.gov.pk  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Lady reading hospital  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**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**  
lady reading hospital  
**Full name of responsible person**  
aiza ur rahman  
**Position**  
trainee medical officer  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
old city near bala hisar fort

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Lady reading hospiatl  
**Full name of responsible person**  
Muhammad Fahim  
**Position**  
Trainee medical officer  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dermatology  
**Street address**  
old city near bala hisar fort  
**City**  
peshawar  
**Province**  
kpk  
**Postal code**  
25100  
**Phone**  
+92 346 5354921  
**Email**  
clinicaldermatologist@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
lady reading hospital  
**Full name of responsible person**  
abdul wasay khan  
**Position**  
trainee medical officer  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
old city,near bala hisar fort  
**City**  
peshawar  
**Province**  
kpk  
**Postal code**  
25100  
**Phone**  
+92 334 9283239  
**Email**

## **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**

Even with de-identification, there's a risk of re-identification. Patient didnot give consent for sharing the data with third party

### **Study Protocol**

No - There is not a plan to make this available

### **Statistical Analysis Plan**

No - There is not a plan to make this available

### **Informed Consent Form**

No - There is not a plan to make this available

### **Clinical Study Report**

No - There is not a plan to make this available

### **Analytic Code**

No - There is not a plan to make this available

### **Data Dictionary**

No - There is not a plan to make this available