Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 terrbinafine for the treatment of childhood dermatophytosis
Design
Randamized 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
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muhammad.faheemyaseen@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 age2-14 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 envolops

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 4thweek

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

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hr@lrh.gov.pk

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Lady reading hospital
Full name of responsible person
Dean
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Phone
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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
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Person responsible for updating data

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Bachelor
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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
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