

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparative efficacy of bifonazole and clotrimazole in the treatment of pityriasis versicolor

Protocol summary

Study aim

aim is to select the optimal treatment for pityriasis versicolor.

Design

Pragmatic, community based, parallel group, not blind, randomised controlled trial.

Settings and conduct

This study will be conducted on patients presenting in dermatology OPD fulfilling the inclusion criteria. Study is Not blinded

Participants/Inclusion and exclusion criteria

60 participants, 30 in each group. All patients who will have clinically pityriasis versicolor lesions as per operational definition within age range of 18-60 years and willing to provide informed consent are included. Patients who are previously treated and are allergic to topical medication are excluded. Patients develop side effects during study also excluded.

Intervention groups

Group A of 30 patients will receive topical bifonazole
Group B of 30 patients will receive topical clotrimazole

Main outcome variables

Efficacy with clinical and mycological cure: yes/no Side effects if any: yes/no

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241028063523N1**
Registration date: **2024-11-06, 1403/08/16**
Registration timing: **registered_while_recruiting**

Last update: **2024-11-06, 1403/08/16**

Update count: **0**

Registration date

2024-11-06, 1403/08/16

Registrant information

Name

Atiya Rahman

Name of organization / entity

Bahria University of Health Sciences Campus Karachi
Pakistan

Country

Pakistan

Phone

+92 21 35319491

Email address

atiyarahman.bumdc@bahria.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-01, 1403/08/11

Expected recruitment end date

2025-04-30, 1404/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative efficacy of bifonazole and clotrimazole in the treatment of pityriasis versicolor

Public title

Comparative efficacy of bifonazole and clotrimazole in the treatment of pityriasis versicolor

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who will have clinically pityriasis versicolor as per operational definition Patients within range of 18-60 years of age Willing to provide informed consent

Exclusion criteria:

Patients with local inflammatory or infectious disease at the site to be treated or who will be allergic to topical medication. Previously treated patients. Patients develop side effects during study.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

All patients presenting in OPD of dermatology Department of PNS Shifa hospital fulfilling inclusion criteria will be included. Patients will be divided into groups using lottery method.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name****Secondary trial Id****Registration date**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of PNS Shifa

Street address

PNS Shifa Hospital, Sailor street DHA phase II, near Kala pul.

City

Karachi

Postal code

75500

Approval date

2024-04-05, 1403/01/17

Ethics committee reference number

ERC/2023/DERM/84

Health conditions studied**1****Description of health condition studied**

Pityriasis versicolor is a chronic cutaneous fungal infection caused by proliferation of lipophilic yeast (malassezia species) in stratum corneum.

ICD-10 code

B36.0

ICD-10 code description

Pityriasis versicolor

Primary outcomes**1****Description**

The primary outcome of the study will focus on mycological cure (negative microscopy of fungal hyphae by potassium hydroxide mount)

Timepoint

Patient will be assessed before intervention, at 2 weeks and 4 weeks after intervention

Method of measurement

Method used to assess mycological cure will be skin scraping mount with potassium hydroxide (negative for fungal hyphae)

2**Description**

The primary outcome of the study will focus on alleviation of physical symptoms such as lesion clearance, erythema, pruritis, desquamation and absence of yellow fluorescence on wood's lamp examination.

Timepoint

Patient will be assessed Before intervention, at 2 weeks and 4 weeks after intervention

Method of measurement

Method used to assess clinical cure will be wood's lamp examination (absence of clinical signs)

Secondary outcomes**1****Description**

tolerability of drugs by monitoring side effects

Timepoint

At 2 weeks and at 4 weeks

Method of measurement

i will measure clinical cure by wood's lamp examination (absence of signs) and mycological cure by skin scraping (negative for fungal hyphae) and side effects (if any)

Intervention groups

1

Description

Clinically and mycologically confirmed cases of Pitryasis versicolor shall be divided into 2 groups. Group 1 and Group 2. INTERVENTION GROUP 1 will have 30 patients and they will be receiving bifonazole 1% w/w cream under trade name of BIFOMYK(manufactured by Bioglan pharma. Pakistan) topical application twice daily for a period of 4 weeks. Response to treatment,disease recurrence and any local or systemic side effects will be checked after 2 and 4 weeks from starting the treatment and they will be followed up for 1 month after stopping the treatment,clinically and with lab investigations by absence of yellow florescence on wood's lamp examination and absence of fungal hyphae on microscopy after scrapping mount with potassium hydroxide. Patients will be advised at the time of prescription to apply thin layer of cream that would be absorbed over lesions. Otherwise there is no educational session in this study. The response of treatment shall be entered in pre designed performa to assess the efficacy of 2 therapeutic agents bifonazole and clotrimazole clinically by by absence of yellow florescence on wood's lamp examination and absence of fungal hyphae on microscopy after scrapping mount with potassium hydroxide. The data will be entered and analyzed by using SPSS statistical package version 21 software .

Category

Treatment - Drugs

2

Description

INTERVENTION GROUP 2 will have 30 patients and they will be receiving clotrimazole 1% w/w cream under trade name of CANESTEN (manufactured by Bayer pakistan pvt. Ltd), topical application twice daily for a period of 4 weeks. Response to treatment, disease recurrence and any local or systemic side effects will be checked after 2 weeks, 4 weeks from starting the treatment and they will be followed up for 1 month after stopping the treatment, clinically and with lab investigation by absence of yellow florescence on wood's lamp examination and absence of fungal hyphae on microscopy after scrapping mount with potassium hydroxide. Patients will be advised at the time of prescription to apply small amount of cream that would be absorbed over lesions. Otherwise there is no educational session in this study. The response of treatment shall be entered in pre designed performa to assess the efficacy of 2 therapeutic agents bifonazole and clotrimazole clinically by by absence of yellow florescence on wood's lamp examination and absence of fungal hyphae on microscopy after scrapping mount with potassium hydroxide. The data will be entered and analyzed by using SPSS statistical package version 21 software

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

PNS Shifa Hospital

Full name of responsible person

Dr Sana Saleem

Street address

PNS shifa Hospital

City

Karachi

Postal code

75500

Phone

+92 21 48506540

Email

sanasaleem2694@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Armed forces Hospital PNS Shifa Karachi,Pakistan

Full name of responsible person

Dr Sana Saleem

Street address

DHA phase II, PNS Shifa hospital, near Kala pul.

City

Karachi

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75500

Phone

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Email

sanasaleem20694@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Armed forces Hospital PNS Shifa Karachi,Pakistan

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Armed forces Hospital, PNS Shifa

Full name of responsible person

Dr Atiya Rahman

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Sailor street, DHA phase II, PNS Shifa

City

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Postal code

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Email

sanasaleem20694@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Armed forces Hospital, PNS shifa

Full name of responsible person

Dr Atiya Rahman

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

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75500

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Email

sanasaleem20694@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Armed forces hospital, PNS shifa

Full name of responsible person

Dr Sana Saleem

Position

Post graduate resident

Latest degree

Bachelor

Other areas of specialty/work

Dermatology

Street address

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City

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Phone

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Email

sanasaleem20694@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

APPENDIX 1: PERFORMA Name, age, gender, address, contact number, weight, height, duration of disease, site group (A,B) INFORMED CONSENT.

When the data will become available and for how long

After 6 months RCT, for 4 years.

To whom data/document is available

primary investigator

Under which criteria data/document could be used

All patients in dermatology opd according to operational definition of pityriasis versicolor fulfilling the inclusion criteria.

From where data/document is obtainable

administration of PNS SHIFA HOSPITAL

What processes are involved for a request to access data/document

contact to primary investigator

Comments