

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 18-60years 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 who 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**

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 Pityriasis 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 fluorescence on wood's lamp examination and absence of fungal hyphae on microscopy after scraping 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 fluorescence on wood's lamp examination and absence of fungal hyphae on microscopy after scraping 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 fluorescence on wood's lamp examination and absence of fungal hyphae on microscopy after scraping 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 fluorescence on wood's lamp examination and absence of fungal hyphae on microscopy after scraping 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

#### Postal code

75500

#### Phone

+92 21 48506540

#### 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**

Karachi

**Province**

Sindh

**Postal code**

75500

**Phone**

+92 21 48506540

**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

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75500

**Phone**

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## 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**

sailors street DHA phase II, near kala pul

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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**