Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Study aim
aim is to select the optimal treatment for pitryasis 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 fullfilling the incluaion criteria. Study is Not blinded
Participants/Inclusion and exclusion criteria
60 participants, 30 in each group. All patients who will have clinically pitryasis versicolor leisions as pe 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 recieve topical bifonazole
Group B of 30 patients will recieve 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
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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 pitryasis versicolor

Public title
Comparative efficacy of bifonazole and clotrimazole in the treatment of pitryasis versicolor
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
All patients who will have clinically pitryasis 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 of infectious disease at the site to be treated or who will be allergic to topical medication Previously treated patients Patients delevelop 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 ll, 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
Pitryasis 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 scrapping 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 leision clearence ,erythema, pruritis, desqamation and absence of yellow floresence 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 woods lamp examination(absence of signs) and mycological cure by skin scrapping (negative for fungal hyphae) and side effects (if any)

Intervention groups

1

Description

Clinically and mycologically confirmed cases of Pityrasis versicolor shall be divided into 2 groups. Group 1 and Group 2. INTERVENTION GROUP 1 will have 30 patients and they will be recieving 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 floresence on wood's lamp examination and absence of fungal hyphae on microscopy after scrapping mount with potassium hydroxide. Patients will be adviced at the time of prescription to apply thin layer of cream that would be absorbed over leisions. 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 floresence 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 recieving 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 systemuc 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 floresence on woods lamp examination and absence of fungal hyphae on microscopy after scrapping mount with potassium hydroxide. Patients will be adviced at the time of prescription to apply small amout of cream that would be absorbed over leisions. 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 floresence 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 ll, PNS Shifa hospital, near Kala pul.
City
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75500
Phone
+92 21 48506540
Email
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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

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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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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

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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 pitryasis versicolor fullfilling 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