Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparative efficacy of combined treatment with ketoconazole 2% cream and adapalene 0.1% gel versus ketoconazole 2% cream monotherapy in pityriasis versicolor.

Protocol summary

Study aim

The objective of this study is to evaluate the effectiveness of combined treatment with Ketoconazole 2% Cream and Adapalene 0.1% Gel versus Ketoconazole 2% Cream alone in the management of Pityriasis Versicolor. The study aims to compare clinical outcomes, including symptom resolution, improvement in lesion count, and patient satisfaction between the two treatment regimens.

Design

Community-based, parallel group, non-blind, randomized controlled trial

Settings and conduct

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

Participants/Inclusion and exclusion criteria

Inclusion criteria for the study are diagnosed cases of Pityriasis Versicolor, patients aged 18–60 years of either sex, and those willing to provide informed consent. The exclusion criteria include patients with known hypersensitivity or allergy to Ketoconazole or Adapalene, concurrent diseases such as hyperthyroidism or hyperhidrosis, pregnant or lactating women, and individuals who have received treatment within the last 8 weeks.

Intervention groups

Group A will receive a combined treatment of Ketoconazole 2% Cream and Adapalene 0.1% Gel, applied once daily for two weeks. Group B will receive Ketoconazole 2% Cream alone, applied once daily for the same duration

Main outcome variables

Clinical improvement (more than 50% improvement in lesions), negative fluorescence on Wood's lamp examination, and a negative result on KOH examination of skin scrapings after four weeks of treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241028063523N4**
Registration date: **2024-11-27, 1403/09/07**
Registration timing: **registered_while_recruiting**

Last update: **2024-11-27, 1403/09/07**
Update count: **0**

Registration date

2024-11-27, 1403/09/07

Registrant information

Name

Atiya Rahman

Name of organization / entity

Bahria University of Health Sciences Campus Karachi Pakistan

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-19, 1403/08/29

Expected recruitment end date

2025-05-19, 1404/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative efficacy of combined treatment with ketoconazole 2% cream and adapalene 0.1% gel versus ketoconazole 2% cream monotherapy in pityriasis versicolor.

Public title
Comparative efficacy of combined treatment with ketoconazole 2% cream and adapalene 0.1% gel versus ketoconazole 2% cream monotherapy in pityriasis versicolor.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosed cases of pityriasis versicolor lesions (as per operational definition) with disease involving total body surface area. Patients within the age range of 18–60 years of either sex Willing to provide informed consent.
Exclusion criteria:
Patients with known hypersensitivity/allergy to Ketoconazole or Adapalene, patients with concurrent diseases (hyperthyroidism or hyperhidrosis) and pregnant/ lactating mothers, previous treatment taken 8 weeks back will be excluded from the 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**
More than 1 sample in each individual
Number of samples in each individual: **1**
NO

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

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee PNS SHIFA
Street address
PNS Shifa Hospital, Sailor street DHA phase ll, near Kala pul.
City
Karachi
Postal code
07557

Approval date
2024-11-18, 1403/08/28

Ethics committee reference number
ERC/2024/Derma/123

Health conditions studied

1

Description of health condition studied
Pityriasis versicolor is a common yeast infection of the skin, in which flaky discolored patches appear on the chest and back. The term pityriasis is used to describe skin conditions in which the scale appears similar to bran. The multiple colors of pityriasis versicolor give rise to the second part of the name, versicolor. Pityriasis versicolor is sometimes called tinea versicolor, although the term tinea should strictly be used for dermatophyte fungus infections.

ICD-10 code
B36.0

ICD-10 code description
Pityriasis versicolor

Primary outcomes

1

Description
Clinical improvement: More than 50% improvement in clinical signs of Pityriasis Versicolor. Negative fluorescence: Absence of yellow fluorescence on Wood's lamp examination of lesions. Negative KOH test: Absence of fungal elements in skin scrapings after four weeks of treatment

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

Method of measurement
Clinical Examination: Observation of improvement in clinical signs such as scaling, pigmentation (hyperpigmentation or hypopigmentation), and lesion appearance. A more than 50% reduction in clinical signs is considered effective. Wood's Lamp Examination: Use of Wood's lamp to detect yellow fluorescence characteristic of Pityriasis Versicolor lesions. Negative fluorescence after treatment indicates efficacy. KOH Examination: Skin scrapings from lesions examined

under a microscope after applying potassium hydroxide (KOH) to identify fungal elements. Absence of fungal elements after treatment confirms effectiveness. Photographic Evidence: Photographs of lesions taken before and after treatment to document changes. Demographic and Baseline Data: Collection of patient details, including age, sex, BMI, duration of the disease, and lesion size, which could influence treatment outcomes. Follow-Up Schedule: Re-evaluation at two weeks and four weeks post-treatment initiation using the above assessments.

Secondary outcomes

1

Description
Side Effects: Monitoring and documenting adverse effects related to the treatments, such as skin irritation, dryness, or allergic reactions.
Timepoint
At 2 weeks and at 4 weeks
Method of measurement
Patient Self-Report: Patients will be asked to report any discomfort, such as irritation, dryness, or allergic reactions during follow-up visits. Documented using a standardized proforma. Clinical Observation: inspect the treated areas for signs of adverse reactions, such as redness, peeling, or swelling.

Intervention groups

1

Description
Confirmed cases of Pityriasis versicolor will be divided into 2 groups. Group 1 and Group 2. (Group A) will receive a combination therapy consisting of Adapco Gel 0.1% (Adapalene) and Conaz Cream 2% (Ketoconazole). Participants in this group will apply both treatments once daily for a duration of two weeks. Conaz Cream 2%, an antifungal agent, works by inhibiting ergosterol synthesis, effectively targeting the Malassezia species responsible for Pityriasis Versicolor. Adapco Gel 0.1%, a retinoid, reduces hyper keratinization and promotes skin renewal while enhancing the antifungal's penetration, creating a synergistic therapeutic effect. The efficacy of this combination therapy will be evaluated through improvement in clinical signs, absence of yellow fluorescence under Wood's lamp, and negative results on KOH testing at two-week and four-week follow-ups.
Category
Treatment - Drugs

2

Description
Group B will receive Conaz Cream 2% (Ketoconazole) as monotherapy. Participants will apply the cream once daily for a duration of two weeks, focusing on the affected areas. As the standard treatment, Conaz Cream 2% targets fungal growth and is effective in managing symptoms of Pityriasis Versicolor. Efficacy will be assessed using the same parameters as the intervention group: improvement in clinical signs, absence of yellow fluorescence under Wood's lamp, and negative KOH test results. Comparison with the intervention group will determine if the addition of Adapco Gel 0.1% offers significant advantages.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
PNS Shifa Hospital
Full name of responsible person
Dr Sunaina Kumari
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DHA phase ll, PNS Shifa Hospital near Kala pul.
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Phone
+92 21 48506540
Email
Sunainap7@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Armed forces Hospital PNS Shifa Karachi,Pakistan.
Full name of responsible person
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Phone
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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
Academic

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 updating data

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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: PROFORMA EFFICACY OF COMBINED TREATMENT WITH KETOCONAZOLE 2% CREAM AND ADAPALENE 0.1% GEL VS. KETOCONAZOLE 2% CREAM MONOTHERAPY IN PITYRIASIS VERSICOLOR – A RANDOMIZED CONTROLLED TRIAL Name: _____ Age (years): _____ Gender: Male/Female Height (m): _____ Weight (kg): _____ BMI (kg/m2): _____ Duration (weeks): _____ Size of lesion (cm): _____ Group: A(COMBINATION) Group: B (MONOTHERAPY) SIDE EFFECTS IF ANY: _____ OUTCOME VARIABLE: EFFICACY: YES/NO
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