Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Efficacy of itraconazole in the prevention of recurrence of Pityriasis Versicolor

Protocol summary

Study aim
To assess the efficacy of short-term, pulsed itraconazole regimen compared to placebo in preventing the recurrence of PV following successful initial treatment over a 4 month period.

Design
Community based, parallel group, double blind, randomized controlled trial.

Settings and conduct
All participants will receive initial treatment with itraconazole (Cap Itraconazole 100mg twice daily for 7 DAYS).Following successful initial treatment after 1 week, cured participants will be randomly assigned to either the itraconazole group (Group A) or the placebo group (Group B).Group A will receive Cap Itraconazole 200mg twice a day in a month for 4 consecutive months and Group B will receive placebo. Participants will be assessed with scheduled follow-up visits on monthly intervals for 4 months and then after further 2 months to see sustained response Study will be conducted in Cmh quetta

Participants/Inclusion and exclusion criteria
Inclusion criteria ● Confirmed diagnosis of PV by clinical examination supported by Wood’s lamp examination ● Age range:13 to 50 years ● Not taken antifungal medication in previous 1 month ● Ability to adhere to treatment and follow-up visits Exclusion criteria ● Known hypersensitivity to itraconazole or other triazole antifungals ● Liver disease or abnormal liver function tests ● Pregnancy or Nursing mother ● Concurrent use of medications known to interact with itraconazole ● Active fungal infections other than PV ● Immunodeficiency or immunosuppressive therapy ● Any other medical condition deemed a safety risk

Intervention groups
After initial treatment,Group A will receive Cap Itraconazole 200mg twice a day in a month for 4 consecutive months and Group B will receive placebo.

Main outcome variables
Treatment of Pityriasis versicolor based on clinical response and negative wood's lamp examination.

General information

Reason for update

Acronym
pityriasis versicolor PV

IRCT registration information
IRCT registration number: **IRCT20210823052264N8**
Registration date: **2024-09-15, 1403/06/25**
Registration timing: **registered_while_recruiting**

Last update: **2024-09-15, 1403/06/25**
Update count: **0**

Registration date
2024-09-15, 1403/06/25

Registrant information

Name
Najia Ahmed

Name of organization / entity
PNS shifa

Country
Pakistan

Phone
+92 81 2864092

Email address
najiaomer@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-08-21, 1403/05/31

Expected recruitment end date
2025-02-21, 1403/12/03

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of itraconazole in the prevention of recurrence of Pityriasis Versicolor

Public title
Efficacy of itraconazole in the prevention of recurrence of Pityriasis Versicolor
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed diagnosis of pityriasis versicolor based on clinical examination supported by Wood's lamp examination Not taken antifungal medication in previous 1 month Ability to adhere to treatment and follow-up visits
Exclusion criteria:
Known hypersensitivity to itraconazole or other triazole antifungals Liver disease or abnormal liver function tests Pregnancy or nursing mother Concurrent use of medications known to interact with itraconazole Active antifungal infections other than pityriasis versicolor Immunodeficiency or immunosuppressive therapy Any other medical condition deemed a safety risk by the investigator
Age
From **13 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **144**
Randomization (investigator's opinion)
Randomized
Randomization description
All participants will receive initial treatment with itraconazole (Cap Itraconazole 100mg twice daily for 7 DAYS).Following successful initial treatment after 1 week, cured participants will be randomly assigned by lottery method to either the itraconazole group (Group A) or the placebo group (Group B).Group A will receive Cap Itraconazole 200mg twice a day in a month for 4 consecutive months and Group B will receive placebo. Participants will be assessed with scheduled follow-up visits on monthly intervals for 4 months and then after further 2 months to see sustained response. The date of any recurrence and details of the lesions or any adverse events will also be documented during follow-up visits.
Blinding (investigator's opinion)
Double blinded
Blinding description
Double blinded study (participant and data analyser are blinded)
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Institutional ethical review board (IERB) certificate - CMH Quetta
Street address
cmh quetta
City
quetta
Postal code
08762
Approval date
2024-08-21, 1403/05/31
Ethics committee reference number
CMH QTA-IERB/37/2024

Health conditions studied

1

Description of health condition studied
Pityriasis Versicolor
ICD-10 code
B36.0
ICD-10 code description
Pityriasis versicolor

Primary outcomes

1

Description
Skin lesions consistent with pityriasis versicolor
Timepoint
before start of study then 1 week, 1,2,3,4 and 6 months after treatment
Method of measurement
clinical examination and woods lamp examination

Secondary outcomes

1

Description
any side effects during itraconazole treament
Timepoint
1 week, 1,2,3,4 and 6 months after treatment

Method of measurement
interviewing with the patients and clinical examination

Intervention groups

1

Description
Intervention group: Group A will receive Cap Itraconazole 200mg twice a day in a month for 4 consecutive month. Ferozsons laboratory (cap icon 100mg)
Category
Treatment - Drugs

2

Description
Control group: Group B will receive placebo once a day in a month for 4 consecutive month.Martin dow multibionata (multivitamin cap) used as placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Combined Military Hospital Quetta
Full name of responsible person
Zara Babar
Street address
CMH Quetta
City
Quetta
Postal code
08762
Phone
+92 331 4005972
Email
zara.babar@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Combined Military Hospital Quetta
Full name of responsible person
Zara Babar
Street address
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08762
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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
Combined Military Hospital Quetta
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
Combined Military Hospital Quetta
Full name of responsible person
Zara Babar
Position
Trainee registrar
Latest degree
Subspecialist
Other areas of specialty/work
Dermatology
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Person responsible for scientific inquiries

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Combined Military Hospital Quetta
Full name of responsible person
Zara Babar
Position
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Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Combined Military Hospital Quetta

Full name of responsible person
Zara Babar

Position
Trainee registrar

Latest degree
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Other areas of specialty/work
Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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

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

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