

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 treatment

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. Ferozs 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

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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**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

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Person responsible for updating data

Contact

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Combined Military Hospital Quetta
Full name of responsible person
Zara Babar
Position
Trainee registrar
Latest degree
Subspecialist
Other areas of specialty/work
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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