

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy of itraconazole in the prevention of recurrence of Pityriasis Versicolor

#### Protocol summary

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

#### 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

#### 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

Zara Babar

##### Street address

CMH Quetta

##### City

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##### Postal code

08762

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zara.babar@yahoo.com

## 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

#### Street address

CMH Quetta

#### City

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#### Province

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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

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zara.babar@yahoo.com

## 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**  
Subspecialist  
**Other areas of specialty/work**  
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zara.babar@yahoo.com

## 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