

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy of Acyclovir in Pityriasis rosea, a double blind randomized controlled trial in a tertiary care hospital in Pakistan.

#### Protocol summary

2023-02-06, 1401/11/17

#### Study aim

This study aims to determine the effectiveness of acyclovir versus placebo in patients presenting with pityriasis rosea as acyclovir may have a potential role in the treatment of pityriasis rosea.

#### Design

Clinical trial which is parallel group, double blind, randomized, phase 3 trial.

#### Settings and conduct

Dermatology department PNS Shifa hospital Karachi

#### Participants/Inclusion and exclusion criteria

Inclusion criteria Patients presenting with pityriasis rosea with either gender between Age 12-70 years. Exclusion criteria patients with positive VDRL test, females with pregnancy or lactation, patients who have taken any other specific treatment for PR in last 01 week, patients with history of CRF and DM, HIV positive and patients with any cause of immunosuppression.

#### Intervention groups

Intervention group 1. Patients were treated with oral acyclovir 800mg 5 times/day for a duration of 7 days. Intervention group 2 Patients were treated with placebo pill (glucose) 5 times/day daily for a duration of 7 days.

#### Main outcome variables

Clinical Response

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210823052264N2**

Registration date: **2023-02-06, 1401/11/17**

Registration timing: **prospective**

Last update: **2023-02-06, 1401/11/17**

Update count: **0**

##### Registration date

#### 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

2023-02-10, 1401/11/21

#### Expected recruitment end date

2023-08-10, 1402/05/19

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Efficacy of Acyclovir in Pityriasis rosea, a double blind randomized controlled trial in a tertiary care hospital in Pakistan.

#### Public title

Efficacy of Acyclovir in Pityriasis rosea

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients presenting with pityriasis rosea within first week of eruption of papulosquamous rash. Either gender

between Age 12-70 years.

**Exclusion criteria:**

Positive venereal disease research laboratory (VDRL) test. Females with pregnancy or lactation. Patients who have taken any other specific treatment for PR in last 01 week. Patients with any cause of immunosuppression like chronic renal failure, diabetes mellitus, HIV positive and malignancy etc.

**Age**

From **12 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Lottery method in the form of sealed envelopes

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The participant, principle investigator, outcome assessors and care givers will all be blinded except for one physician who will open the sealed envelope and give the patient drug or placebo, as per the group code inside the envelope, without informing the patient if he is being given the drug or placebo

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethical Review Committee, PNS shifa

**Street address**

PNS Shifa Hospital, DHA phase 2, Karachi

**City**

Karachi

**Postal code**

75500

**Approval date**

2023-02-01, 1401/11/12

**Ethics committee reference number**

ERC/2023/DERM/01

**Health conditions studied**

**1**

**Description of health condition studied**

Pityriasis rosea

**ICD-10 code**

L42

**ICD-10 code description**

Pityriasis rosea

**Primary outcomes**

**1**

**Description**

Clinical Response based on clearance of lesions.

**Timepoint**

Patients in both the groups were evaluated clinically on 7th and 14th day of treatment

**Method of measurement**

Clinical Response Evaluation

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: In group "A" patients were treated with oral acyclovir 800mg 5 times/day for a duration of 7 days

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: In group "B" patients were treated with placebo pill (glucose) 5 times/day daily for a duration of 7 days.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

PNS Shifa Hospital

**Full name of responsible person**

Dr Najia Ahmed

**Street address**

Main Korangi Rd, near Kala Pul, Clifton, Karachi, Karachi City, Sindh

**City**

Karachi  
**Postal code**  
74900  
**Phone**  
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**Email**  
najiaomer@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
PNS SHIFA  
**Full name of responsible person**  
Dr Najia Ahmed  
**Street address**  
Main Korangi Rd, near Kala Pul, Clifton, Karachi,  
Karachi City, Sindh  
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Karachi  
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**Email**  
najiaomer@yahoo.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
PNS SHIFA  
**Proportion provided by this source**  
100  
**Public or private sector**  
Private  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Persons

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
PNS shifa  
**Full name of responsible person**  
Najia Ahmed  
**Position**  
Consultant  
**Latest degree**  
Specialist

#### Other areas of specialty/work

Dermatology  
**Street address**  
Dr najia ahmed 5th floor OPD tower PNS shifa hospital  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
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**Position**  
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## Person responsible for updating data

#### Contact

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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**

Yes - There is a plan to make this available

### **Title and more details about the data/document**

Primary outcome

### **When the data will become available and for how long**

1 month after publication and for life time.

### **To whom data/document is available**

People Working in academic institutions

### **Under which criteria data/document could be used**

Many

### **From where data/document is obtainable**

najaomer@yahoo.com

### **What processes are involved for a request to access data/document**

Request

### **Comments**