

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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	
<u>1</u>	
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	
<u>1</u>	
Description of health condition studied	
Pityriasis rosea	
ICD-10 code	
L42	
ICD-10 code description	
Pityriasis rosea	
Primary outcomes	
<u>1</u>	
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	
<u>1</u>	
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	
<u>2</u>	
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	
<u>1</u>	
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
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Fax
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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
City
Karachi
Postal code
74900
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Fax
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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

PNS shifa

Full name of responsible person

Najia Ahmed

Position

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Person responsible for updating data

Contact

Name of organization / entity

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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

najiaomer@yahoo.com

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

Request

Comments