Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

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
2023-02-06, 1401/11/17

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

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
PNS SHIFA
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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
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
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Person responsible for updating data

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Email

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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