

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative analysis of efficacy and safety of oral versus subcutaneous methotrexate in severe psoriasis in tertiary care hospital

#### Protocol summary

##### Study aim

To compare the safety and efficacy of oral and subcutaneous routes of administration of methotrexate in patients with severe psoriasis

##### Design

Total 60 patients will be randomized by lottery method into two equal groups with 30 patients in each group (sample size calculated by WHO sample size calculator)

##### Settings and conduct

National University of Medical Sciences in collaboration with dermatology department of PEMH

##### Participants/Inclusion and exclusion criteria

inclusion criteria 1. Both gender, aged between 18 and 65 years 2. Severe psoriasis PGA score of 4 exclusion criteria 1. Pregnant or lactating women 2. Any respiratory, cardiac, GI, hepatic, or renal illness 3. Patients on biologics

##### Intervention groups

intervention group 1 :will receive oral Methotrexate (10 mg up to 25 mg) weekly. intervention group 2 :will receive subcutaneous Methotrexate (10 mg up to 25 mg) weekly

##### Main outcome variables

PGA score Adverse effects including number of episodes of vomiting and diarrhea laboratory investigation for Hb level, serum ALT, serum AST, urea and creatinine levels.

#### General information

##### Reason for update

##### Acronym

none

##### IRCT registration information

IRCT registration number: **IRCT20231010059674N1**

Registration date: **2024-12-12, 1403/09/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-12-12, 1403/09/22**

Update count: **0**

##### Registration date

2024-12-12, 1403/09/22

##### Registrant information

##### Name

Mehwish Amin

##### Name of organization / entity

National University of Medical Sciences, Pakistan

##### Country

Pakistan

##### Phone

+92 51 5488638

##### Email address

mehwishlaeeq8@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-05-01, 1403/02/12

##### Expected recruitment end date

2025-05-01, 1404/02/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative analysis of efficacy and safety of oral versus subcutaneous methotrexate in severe psoriasis in tertiary care hospital

##### Public title

Comparative analysis of efficacy and safety of oral versus subcutaneous methotrexate in severe psoriasis in tertiary care hospital

##### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients having severe psoriasis with PGA score 4 will be included in the study. Patients on biologics for last 1 year

### Exclusion criteria:

Pregnant or lactating women Patients with any major respiratory, cardiac, GI, hepatic, or renal illness Patients on biologics within last 1 year Unwilling for monthly follow-up.

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

4

## Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Coding will be done by the dermatologist. Patients will be randomised into two groups by lottery method. The code will be chosen by the patient.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this single blind study the researcher (outcome assessor )will be blinded. The treating dermatologist and the patients will be aware of the treatment provided with the label of " intention to treat single blind study"

## Placebo

Not used

## Assignment

Parallel

## Other design features

patients will be followed for 12 weeks with monthly followup

## Secondary Ids

### 1

#### Registry name

PEMH rawalpindi

#### Secondary trial Id

19/2024

#### Registration date

2024-03-15, 1402/12/25

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethical committee Pak- emirates military hospital  
Rawalpindi

#### Street address

Abid Majeed Road Rawalpindi

#### City

Rawalpindi

#### Postal code

46000

#### Approval date

2024-03-15, 1402/12/25

#### Ethics committee reference number

A/28/ERC/19/2024

## Health conditions studied

### 1

#### Description of health condition studied

psoriasis

#### ICD-10 code

L40.9

#### ICD-10 code description

Psoriasis, unspecified

## Primary outcomes

### 1

#### Description

PGA score

#### Timepoint

4 weeks

#### Method of measurement

PGA score, heamoglobin level, serum ALT, serum AST, urea, Creatinine

## Secondary outcomes

### 1

#### Description

relapse.

#### Timepoint

16 weeks

#### Method of measurement

PGA score

## Intervention groups

### 1

#### Description

Control group: oral route is considered gold standard treatment in severe psoriasis so it will be considered as control group. Patients will receive 10-25 mg /week oral Methotrexate for 3 months with weekly followup. Monthly followup will be done for next 3 months to check for relapse.

#### Category

Treatment - Drugs

## 2

### Description

Intervention group: Patients in this group will receive methotrexate in a dose of 10-25 mg weekly by subcutaneous route and will be followed up weekly for 3 months. Afterwards they will be followed for relapse by monthly visits for next 3 months.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Pak emirates military hospital

**Full name of responsible person**

Mehwish Amin

**Street address**

Abid Majeed road,Rawalpindi

**City**

Rawalpindi

**Postal code**

46000

**Phone**

+92 51 9273480

**Fax****Email**

mehwishlaeeq8@gmail.com

**Web page address**

[https://en.wikipedia.org/wiki/Military\\_Hospital\\_Rawalpindi](https://en.wikipedia.org/wiki/Military_Hospital_Rawalpindi)

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

national university of medical sciences

**Full name of responsible person**

Mehwish laeeq

**Street address**

abid ,majeed road rawalpindi

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rawalpindi

**Postal code**

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**Phone**

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**Fax****Email**

info@numspak.edu.pk

**Web page address**

<http://numspak.edu.pk>

**Grant name**

NUMS research fund

**Grant code / Reference number**

12345

**Is the source of funding the same sponsor****organization/entity?**

Yes

**Title of funding source**

national university of medical sciences

**Proportion provided by this source**

50

**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**

National University of Medical Sciences

**Full name of responsible person**

Mehwish Amin

**Position**

Demonstrator

**Latest degree**

Master

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Abid Majeed Road<Rawalpindi

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**Province**

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**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

National University of Medical Sciences

**Full name of responsible person**

Mehwish Amin

**Position**

instructor

**Latest degree**

Master

**Other areas of specialty/work**

Medical Pharmacy

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**Web page address**<http://numspak.edu.pk>**Email**

mehwishlaeeq8@gmail.com

**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**

Comparative Analysis of Efficacy and Safety of Oral Versus Subcutaneous Methotrexate in Severe Psoriasis in Tertiary Care Hospital

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

12 months

**To whom data/document is available**

academic

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

article

**From where data/document is obtainable**

google scholar

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

internet

**Comments**

no

**Person responsible for updating data****Contact****Name of organization / entity**

NUMS rawalpindi

**Full name of responsible person**

sakina sadiq

**Position**

associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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