

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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Abid Majeed road,Rawalpindi

City

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mehwishlaeeq8@gmail.com

Web page address

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

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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

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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

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<http://numspak.edu.pk>

Person responsible for updating data

Contact

Name of organization / entity
NUMS rawalpindi
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sakina sadiq
Position
associate professor
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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

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