Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Medica Sciences in collaboration wit 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

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+92 51 5488638

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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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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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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
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Person responsible for updating data

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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