# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## OUTCOME OF TOPICAL DAPSONE 5% VERSUS TOPICAL CLINDAMYCIN 1% IN TREATMENT OF MILD TO MODERATE ACNE VULGARIS

## Protocol summary

**Study aim**

To compare the outcome of treatment of topical 5% dapsone versus topical 1% clindamycin in treatment of mild to moderate acne vulgaris at Allama Iqbal Memorial Teaching Hospital, Sialkot, Pakistan.

**Design**

Randomized Controlled Trial

**Settings and conduct**

Department Of Dermatology, Allama Iqbal Memorial Teaching Hospital, Sialkot, Pakistan

**Participants/Inclusion and exclusion criteria**

Inclusion Criteria:  Patients of either gender, between 18-60 years of age, presenting with mild to moderate acne vulgaris as per operational definition will be included in the study. Exclusion Criteria:  Pregnant patients and Lactating mothers.  Patients do not take any oral antibiotics for 4 weeks and topical antibiotics for 2 weeks.  Patients have other facial conditions besides acne vulgaris (e.g., rosacea).  Patients taking Glucocorticoids, Phenytoin, Isoniazid and Lithium  Patients with history of allergy with the study medication

**Intervention groups**

Patients with Mild to Moderate Acne Vulgaris as per the Global Acne Grading System will be randomly allocated using sealed opaque envelops bearing A= Clindamycin 1% gel group and B= Dapsone 5% gel group. Dapsone gel topically will be applied at bedtime on the lesions daily for 12 weeks. While clindamycin 1% gel treatment will be applied twice daily for 12 weeks. The outcome of both treatments will be assessed after 12 weeks of treatment in term of Mean GAGS score

**Main outcome variables**

The outcome will be assessed in terms of the mean Global Acne Grading System scores after the 12-week treatment period, defined as follows: 1. Mean GAGS Scores: The primary outcome will be the mean GAGS scores in dapsone 5% group and the clindamycin 1% group at the end of the 12-week treatment period.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20250124064503N1**
Registration date: **2025-02-03, 1403/11/15**
Registration timing: **registered_while_recruiting**

Last update: **2025-02-03, 1403/11/15**
Update count: **0**

**Registration date**

2025-02-03, 1403/11/15

**Registrant information**

**Name**

Muhammad Bilal Iftikhar

**Name of organization / entity**

Khawaja Muhammad Safdar Medical College

**Country**

Pakistan

**Phone**

+92 48 3256011

**Email address**

bilaliftikhar28@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2025-02-03, 1403/11/15

**Expected recruitment end date**

2025-05-03, 1404/02/13

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
OUTCOME OF TOPICAL DAPSONE 5% VERSUS TOPICAL CLINDAMYCIN 1% IN TREATMENT OF MILD TO MODERATE ACNE VULGARIS

**Public title**
To Compare Efficacy and safety of Topical Dapsone 5% versus Topical Clindamycin 1% In Treatment of Mild to Moderate Acne Vulgaris

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Both Males and Females 18-60 Years of age Mild to Moderate Acne Vulgaris as per Global Acne Grading Score

**Exclusion criteria:**
Pregnant patients and Lactating mothers Patients do not take any oral antibiotics for 4 weeks and topical antibiotics for 2 weeks Patients have other facial conditions besides acne vulgaris (e.g.' ,rosacea) Patients taking Glucocorticoids, Phenytoin, Isoniazid and Lithium Patients with history of allergy with the study medication

**Age**
From **18 years** old to **60 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **132**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
A brief history of demographic information and written informed consent will be taken from each patient. Patients will be examined by dermatologists and will be graded. Patients will be randomly allocated using sealed opaque envelops bearing A= Clindamycin 1% gel group and B= Dapsone 5% gel group. Dapsone gel topically will be applied at bedtime on the lesions daily for 12 weeks. While clindamycin 1% gel treatment will be applied twice daily for 12 weeks. The outcome of both treatments will be assessed in 12 weeks of treatment .

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
Research Ethics Committee, Khawaja Muhammad Safdar Medical College, Sialkot

**Street address**
Khawaja Muhammad Safdar Medical College, Sialkot

**City**
Sialkot

**Postal code**
51310

**Approval date**
2024-12-31, 1403/10/11

**Ethics committee reference number**
No:47/REC/KMSMC

## Health conditions studied

**1**

**Description of health condition studied**
Acne Vulgaris

**ICD-10 code**
L70.0

**ICD-10 code description**
Acne vulgaris

## Primary outcomes

**1**

**Description**
The Primary Outcome will be the mean Global Acne Grading System Score in Dapsone 5% group and the Clindamycin 1% group at the end of 12 weeks treatment period

**Timepoint**
12 weeks

**Method of measurement**
Global Acne Grading System Score

## Secondary outcomes

**1**

**Description**
Other Variables like Irritation, Burning Sensation, Pruritis, Erythema and oily skin after use of the Topical Drugs

**Timepoint**
12 weeks

**Method of measurement**
Question will be asked regarding above mentioned side effects

## Intervention groups

**1**

**Description**
Intervention group 1: Dapsone 5% Gel

**Category**

Treatment - Drugs

**2**

**Description**
Intervention group 2: Clindamycin 1%
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Khawaja Muhammad Safdar Medical College/Allama Iqbal Memorial Teaching Hospital, Sialkot
**Full name of responsible person**
Dr Bushra Bashir ( Head Of Department of Dermatology KMSMC/AIMTH, Sialkot)
**Street address**
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**Phone**
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info@kmsmc.edu.pk
**Web page address**
https://kmsmc.edu.pk

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Khawaja Muhammad Safdar Medical College/Allama Iqbal Memorial Teaching Hospital, Pakistan
**Full name of responsible person**
Dr Zareen Saqib( Assistant Professor of Dermatology)
**Street address**
Dermatology Demartment, Khawaja Muhammad Safdar Medical College
**City**
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**Postal code**
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**Phone**
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**Email**
dr.zarex@gmail.com
**Web page address**
https://kmsmc.edu.pk/
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Khawaja Muhammad Safdar Medical College/Allama Iqbal Memorial Teaching Hospital, Pakistan
**Proportion provided by this source**
100
**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**
Khawaja Muhammad Safdar Medical College
**Full name of responsible person**
Muhammad Bilal Iftikhar
**Position**
Post Graduate Resident, Dermatology
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Dermatology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Post Graduate Resident

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Medical doctor

**Other areas of specialty/work**
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**Email**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available