

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 envelopes 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 envelopes 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

Khawaja Muhammad Safdar Medical College, Sialkot

City

Sialkot

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Phone

+92 52 9250738

Email

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

Sialkot

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Phone

+92 336 4220553

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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51310

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