

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative evaluation of Dapsone gel 5% with Adapalene gel 0.1% in patients with acne vulgaris

Protocol summary

Study aim

A comparative study of 5% dapsone gel with 0.1% adapalene gel in patients with acne vulgaris

Design

A clinical trial without a control group, community-based and practice-oriented, parallel groups, double-blind, randomized, phase 3 on 60 patients (30 receiving dapsone and 30 receiving adapalene). A simple randomization method was used for randomization.

Settings and conduct

To investigate the effectiveness of dapsone gel in acne and compare its effect with adapalene gel, patients diagnosed with acne vulgaris with moderate to severe severity who refer to the skin clinic of Imam Khomeini Hospital in Ahvaz are randomly divided into two groups. The first group will receive dapsone gel and the second group will receive adapalene gel. To check the severity of acne, the criterion of the global acne grading system is used. Also, the study is conducted in a double-blind manner (patient and interventionist) so that the gel inside the same container will be given to the patients by a non-interventionist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with moderate to severe inflammatory acne on the face, at least 12 years old.

Exclusion criteria: lactating and pregnant women, people who have received topical and systemic anti-acne treatment within the previous month, cases of mild acne, and a history of allergy to doxycycline, adapalene, and dapsone.

Intervention groups

First group: treatment with 5% dapsone gel twice a day for 2 months. Second group: treatment with 0.1% adapalene gel twice a day for 2 months

Main outcome variables

Number of acne lesions after treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230806059062N1**

Registration date: **2023-08-20, 1402/05/29**

Registration timing: **prospective**

Last update: **2023-08-20, 1402/05/29**

Update count: **0**

Registration date

2023-08-20, 1402/05/29

Registrant information

Name

Kosar Gholipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 114 3709

Email address

gholipour.k@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of Dapsone gel 5% with Adapalene gel 0.1% in patients with acne vulgaris

Public title

Effect of Dapsone gel 5% in the treatment of patients with acne vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with moderate to severe inflammatory acne on the face

Exclusion criteria:

Pregnant and lactating women History of using systemic anti-acne treatment drugs in the previous 1 month The presence of inflammatory acne on the trunk without facial involvement Cases of mild acne (the presence of only comedones without inflammatory lesions) Photosensitivity Patients receiving drugs that cause photosensitivity (such as griseofulvin). Age above 30 years and below 12 years Patients with G6pd deficiency (in the group receiving dapsone gel) History of allergy to doxycycline, adapalene and dapsone

Age

From **12 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with eligibility criteria will be divided into two groups using a randomized block design. An online website (<https://www.sealedenvelope.com>) is used to generate a random list based on the desired sample size and block size of 4. After creating a list, each patient will identify with a unique code throughout the study. 30 people are selected for the first intervention group and 30 people for the second intervention group. Then, each number is written on the drug container, which is the same for both groups, and it will be given to the patients by someone other than the interventionist, while the patients are not aware of the contents of the container.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be evaluated by another specialist as part of the main researcher, and the design will be done in a double-blind manner. Medicines are provided to patients in a sealed container by a non-interventionist who is the same for both groups, so that patients will not know about its contents due to the similarity of the two types of gel.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan Hospital Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan blvd- Golestan Hospital

City

Ahvaz

Province

Khuzestan

Postal code

1579461357

Approval date

2023-05-09, 1402/02/19

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1402.030

Health conditions studied

1

Description of health condition studied

Acne

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

Acne severity based on the global acne grading system

Timepoint

Before starting treatment, 1, 2 and 3 months after starting treatment

Method of measurement

Global acne grading system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment with 5% dapsons gel (Pars Behrouzan Jam Company) twice a day for 2 months

Category

Treatment - Drugs

2

Description

Intervention group: Treatment with Adapalene gel 0.1 % (Razak Company) twice a day for 2 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini

Full name of responsible person

Kosar Gholipour

Street address

Azadegan St. - Imam Khomeini Hospital

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Ahvaz

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gholipour.k@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz University of Medical Sciences

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

Ahvaz University of Medical Sciences

Full name of responsible person

Kosar Gholipour

Position

Resident

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

Contact

Name of organization / entity
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Full name of responsible person
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Postal code

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

Not applicable

Data Dictionary

Not applicable