

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6193673166

**Phone**

+98 61 3314 0000

**Email**

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

**Street address**

Ahvaz, Ahvaz Jundishapur University of Medical Sciences

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715794

**Phone**

+98 61 3314 0000

**Email**

zakerkish-m@ajums.ac.ir

**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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gholipour.k@ajums.ac.ir

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**Phone**  
+98 61 3314 0000  
**Email**  
gholipour.k@ajums.ac.ir

## Person responsible for updating data

### 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  
**Street address**  
Azadegan St. - Imam Khomeini Hospital  
**City**  
Ahvaz  
**Province**  
Khouzestan  
**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