Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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. become 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
Khouzestan
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% dapsone 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
Khouzestan

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
Khouzestan

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

Street address
Azadegan St. - Imam Khomeini Hospital

City
Ahvaz

Province
Khouzestan

Postal code
6193673166

Phone
+98 61 3314 0000

Email
gholipour.k@ajums.ac.ir

Person responsible for scientific 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

Street address
Azadegan St. - Imam Khomeini Hospital

City
Ahvaz

Province
Khouzestan

Postal code
6193673166

Phone
+98 61 3314 0000
Fax
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
6193673166
Phone
+98 61 3314 0000
Email
gholipour.k@ajums.ac.ir

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