Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison the effect of Dapsone gel 5% and Benzoyl peroxide gel 5% in the treatment of mild to moderate acne in Sina Hospital in Hamadan

Protocol summary

Study aim
Investigating the effectiveness of 5% dapsone gel and comparing it with 5% benzoyl peroxide gel in the treatment of mild to moderate acne.

Design
Clinical trial without control group, community-based and practice-oriented, parallel groups, single-blind, randomized, phase 3 on 90 patients (45 patients receiving dapsone drug and 45 patients receiving benzoyl peroxide drug). The lottery method was used for randomization.

Settings and conduct
To investigate the effectiveness of dapsone gel in acne and compare its effect with benzoyl peroxide gel, patients diagnosed with acne vulgaris with mild to moderate severity who refer to the skin clinic of Farshchian Hospital in Hamedan are randomly divided into two groups. The first group will receive dapsone gel and the second group will receive benzoyl peroxide gel. To check the severity of acne, the criterion of the global acne grading system is used.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People with mild to moderate acne, aged at least 12 years Exclusion criteria: Pregnant and lactating women, known sensitivity to dapsone gel or benzoyl peroxide gel or preservatives in medicine, history of using systemic drugs in the previous 3 months, history of using topical antibiotics or retinoid compounds in the previous 1 month, history Use of antibacterial soaps or topical exfoliants during the previous 2 weeks.

Intervention groups
First group: treatment with 5% dapsone gel twice a day for 3 months. Second group: treatment with 5% benzoyl peroxide gel once a day for 3 months

Main outcome variables
Number of acne lesions after treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220724055546N1**
Registration date: **2022-08-04, 1401/05/13**
Registration timing: **prospective**

Last update: **2022-08-04, 1401/05/13**
Update count: **0**

Registration date
2022-08-04, 1401/05/13

Registrant information

Name
Javad Rezaiefard

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3827 4191

Email address
javad.rzf@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison the effect of Dapsone gel 5% and Benzoyl peroxide gel 5% in the treatment of mild to moderate acne in Sina Hospital in Hamadan

Public title
Effect of Dapsone gel 5% in the treatment of mild to moderate acne
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient with mild to moderate acne
Exclusion criteria:
Pregnant and lactating women Known sensitivity to dapsone gel or benzoyl peroxide gel or preservatives in the drug History of using systemic drugs in the previous 3 months History of using topical antibiotics or retinoid compounds in the previous 1 month History of using antibacterial soaps or topical exfoliants in the previous 2 weeks
Age
From **12 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the rule of random allocation: the number of samples allocated to each of the studied groups is equal, so that the first intervention group includes 45 people and the second intervention group also includes 45 people. 45 balls for the first intervention group and 45 balls for the second intervention group are placed in a lottery container and then the balls are randomly removed from the container without replacement and the created sequence is recorded.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients will be evaluated by another specialist as part of the main researcher, and the design will be done in a blinded manner
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Mirzadeh Eshghi Blvd., Hamedan town, Sina Hospital
City
Hamedan
Province
Hamadan
Postal code
6516848741
Approval date
2022-06-27, 1401/04/06
Ethics committee reference number
IR.UMSHA.REC.1401.320

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
At the beginning of the treatment, one, two and three months after the treatment
Method of measurement
Global Acne Grading System

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Treatment with 5% dapsone gel twice a day for 3 months
Category
Treatment - Drugs

2

Description
Intervention group: Treatment with 5% Benzoyl peroxide once a day for 3 months
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina hospital
Full name of responsible person
Javad Rezaiefard
Street address
Mirzadeh Eshghi Blvd., Hamedan Town., Sina hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Javad Rezaiefard
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Javad Rezaiefard
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data is transient after de-identifying individuals
When the data will become available and for how long
Access starts 6 months after the results are published
To whom data/document is available
Researchers working in medical institutions
Under which criteria data/document could be used
Evaluation of drug effect based on age and sex
From where data/document is obtainable
Hamedan University of Medical Sciences
What processes are involved for a request to access data/document
Request from the university research unit
Comments