

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 dapson 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

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

City

Hamedan

Province

Hamadan

Postal code

6516848741

Phone

+98 81 3827 4191

Email

Javad.rzf@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Javad Rezaiefard

Street address

Mirzadeh Eshghi Blvd, Hamedan Town, Sina hospital

City

Hamedan

Province

Hamadan

Postal code

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Phone

+98 81 3827 4191

Email

Javad.rzf@gmail.com

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

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

Dermatology

Street address

Mirzadeh Eshghi Blvd., Hamedan Town, Sina hospital

City

Hamedan

Province

Hamadan

Postal code

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Phone

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Email

Javad.rzf@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Javad Rezaiefard

Position

Resident

Latest degree

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Other areas of specialty/work

Dermatology

Street address

Mirzadeh Eshghi Blvd., Hamedan Town, Sina hospital

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Phone

+98 81 3827 4191

Email

Javad.rzf@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

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Javad Rezaiefard

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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