

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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% dapson 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**

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**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

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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**

## 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**

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## Person responsible for scientific inquiries

### Contact

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Hamedan University of Medical Sciences

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Javad Rezaiefard

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Resident

**Latest degree**

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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**