

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison of the efficacy of dapsons 5% gel plus oral doxycycline versus benzoyl peroxide 5% gel plus oral doxycycline in patients with moderate acne vulgaris

#### Protocol summary

##### Study aim

compare the therapeutic effects of Dapsone 5% gel plus oral doxycycline versus Benzoyl peroxide 5% gel plus oral Doxycycline

##### Design

The present study is a double blind randomized clinical trial with a 1 : 1 allocation ratio.

##### Settings and conduct

patients with acne vulgaris aged 18 to 25 years refer to dermatology clinic at Rasht Razi Hospital during September 2017 to March 2018 with inclusion criteria after obtaining informed consent.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria involved the patients with acne vulgaris who have 15-50 inflammatory lesions and 20-100 non-inflammatory lesions (comedones) or the total number of lesions accounts for 30 to 120 (ranked as moderate in the GASS classification). The exclusion criteria included secondary acne due to other diseases or causes, using other oral or topical medicines to treat acne, G6PD deficiency, severe nodular cystic acne (ranked as very severe in the GASS classification), and Acne conglobata.

##### Intervention groups

for intervention group Dapsone 5% gel and for control group topical Benzoyl peroxide 5% gel are prescribed.

##### Main outcome variables

Decrease in inflammatory and non-inflammatory lesions

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017072035195N1**

Registration date: **2017-10-23, 1396/08/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-10-04, 1398/07/12**

Update count: **1**

##### Registration date

2017-10-23, 1396/08/01

##### Registrant information

###### Name

Hojat Eftekhari

###### Name of organization / entity

Guilan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 3355 0028

###### Email address

eftekhari@gums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Deputy of Research and Technology of Guilan University of Medical Sciences

##### Expected recruitment start date

2017-08-23, 1396/06/01

##### Expected recruitment end date

2018-02-20, 1396/12/01

##### Actual recruitment start date

2017-09-23, 1396/07/01

##### Actual recruitment end date

2018-03-19, 1396/12/28

##### Trial completion date

2018-05-22, 1397/03/01

##### Scientific title

Comparison of the efficacy of dapsons 5% gel plus oral doxycycline versus benzoyl peroxide 5% gel plus oral doxycycline in patients with moderate acne vulgaris

##### Public title

Dapson in acne vulgaris

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with acne vulgaris who have 15-50 inflammatory lesions and 20-100 non-inflammatory lesions (comedones) (ranked as moderate in the GASS classification). The total number of lesions accounts for 30 to 120 (ranked as moderate in the GASS classification).

### Exclusion criteria:

Secondary acne due to other diseases or causes Using other oral or topical medicines to treat acne G6PD deficiency Severe nodular cystic acne (ranked as very severe in the GASS classification) Acne conglobata.

## Age

From **18 years** old to **25 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

## Sample size

Target sample size: **60**

Actual sample size reached: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Eligible patients divide into two groups according to the randomized block design. The online website <https://www.sealedenvelope.com> is used to generate a randomized list of study groups. This list is compiled in the website on the basis of the intended sample size, with four-block sizes for 60 patients. After generating a list on the site, each individual is assigned a unique code and identified by it during the study.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The above two topical drugs prepare in similar tubes. The patient, the prescribing physician and outcome assessor are unaware of the drug type. The drugs are provided to the patients at each visit by one of the dermatology ward staff who do not play a role in the diagnosis and treatment of patients.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of University of Medical Sciences

##### Street address

Razi hospital, Sardar Jangal Avenue, Rasht, Guilan, Iran

##### City

Rasht

##### Province

Guilan

##### Postal code

4144895655

#### Approval date

2017-04-29, 1396/02/09

#### Ethics committee reference number

ir.gums.rec.1396.26

## Health conditions studied

### 1

#### Description of health condition studied

Acne vulgaris

#### ICD-10 code

L70.0

#### ICD-10 code description

Acne vulgaris

## Primary outcomes

### 1

#### Description

inflammatory lesion (papule & pustule) non inflammatory (comedone)

#### Timepoint

weeks 2, 4, 8, 12 after treatment

#### Method of measurement

GAAS Score

## Secondary outcomes

### 1

#### Description

Side effects (Erythem, Burning, pruritus, Skin dryness, phototoxicity)

#### Timepoint

weeks 2, 4, 8, 12 after treatment

#### Method of measurement

History and examination

## Intervention groups

### 1

#### Description

In control group , benzoyl peroxide 5% Gel once daily for 3 months is administrated.

**Category**

Treatment - Drugs

**2****Description**

In cases group , Dapson 5% Gel once daily for 3 months is administrated.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Razi hospital, Sardar Jangal Avenue, Rasht, Guilan, Iran

**Full name of responsible person**

Dr Hojat Eftekhri

**Street address**

Razi hospital, Sardar Jangal Avenue, Rasht, Guilan, Iran

**City**

Rasht

**Province**

Guilan

**Postal code**

4144895655

**Phone**

+98 13 3355 0028

**Fax**

+98 13 3353 0169

**Email**

Eftekhari@gums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Dr Shadman Nemati

**Street address**

Deputy of Research and Technology of the Guilan University of Medical Sciences, Shahid Siadati Ave, Namjoo St, Guilan, Rasht, Iran

**City**

Rasht

**Province**

Guilan

**Postal code**

4144666949

**Phone**

+98 13 3333 6394

**Fax**

+98 13 3333 6395

**Email**

research@gums.ac.ir

**Web page address**

http://www.gums.ac.ir/research

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Rasht 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**

Guilan University of Medical Sciences

**Full name of responsible person**

Dr Hojat Eftekhari

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Razi hospital, Sardar Jangal Avenue, Rasht, Guilan, Iran

**City**

Rasht

**Province**

Guilan

**Postal code**

4144895655

**Phone**

+98 13 3355 0028

**Fax**

+98 13 3353 0169

**Email**

EFTEKHARI@GUMS.AC.IR

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Dr Hojat Eftekhari

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Razi hospital, Sardar Jangal Avenue, Rasht, Guilan, Iran

**City**

Rasht

**Province**

Guilan

**Postal code**

4144895655

**Phone**

+98 13 3355 0028

**Fax**

+98 13 3353 0169

**Email**

Eftekhari@gums.ac.ir

**Web page address**

Dermatology

**Street address**

Razi hospital, Sardar Jangal Avenue, Rasht, Guilan, Iran

**City**

Rasht

**Province**

Guilan

**Postal code**

4144895655

**Phone**

+98 13 3355 0028

**Fax**

+98 13 3353 0169

**Email**

dr.saharnabatchii@yahoo.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Dr Sahar Nabarchi Ahmadi

**Position**

Dermatologist Assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

**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**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available