Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the efficacy of dapsone 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

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Deputy of Researh 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 dapsone 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

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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 adminestrated.

Category

Treatment - Drugs

2

Description

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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr Shadman Nemati

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

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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

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

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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