

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of the effect of 40% salicylic acid versus 30% salicylic acid with and without combination with doxycycline in the treatment of moderate acne vulgaris: a double-blinded, randomized, clinical trial

Protocol summary

Study aim

effect of salicylic acid 40% compared to 30% salicylic acid with and without combination with doxycycline in the treatment of moderate acne vulgaris

Design

A double-blind, phase 1 clinical trial with 99 patients will be performed for randomization by permutation blocks with variable size of three and six, and after preparing a list of individuals using web-based randomization, from opaque envelopes will be sealed. And waxed is used by other researchers to hide the randomization process.

Settings and conduct

Research population: Patients with moderate acne vulgaris referred to the dermatology clinic of Allameh Behloul Gonabadi Hospital during the study period Individuals referring to dermatology clinics will be divided into three intervention groups 1, 2, 3 and 3 if they have the conditions to enter the study after the company's consent. Assessments will be determined by your doctor at the beginning of treatment and then every two weeks until the end of treatment and one month after the end of treatment.

Participants/Inclusion and exclusion criteria

Entry requirements: Moderate to severe acne vulgaris (according to the classification system of vampires) • Age over 12 years No entry conditions: • Pregnancy or intending to • Breastfeeding Taking oral and topical acne medications in the last 30 days • History of allergies to drugs used in the study • History of colloid formation • History of light sensitivity • Presence of recurrent herpes simplex infection • The presence of warts on the face and contagious molluscum in patients • Active dermatitis on the face

Intervention groups

The first group: recipients of 30% salicylic acid and doxycycline The second group: recipients of 30% salicylic acid and placebo Group 3: Recipients of 40% salicylic

acid and placebo

Main outcome variables

Improve vulgaris acne

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211102052949N1**

Registration date: **2021-12-20, 1400/09/29**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-20, 1400/09/29**

Update count: **0**

Registration date

2021-12-20, 1400/09/29

Registrant information

Name

Abolfazl Mokhtari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 5729 2003

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-29, 1400/09/08

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of 40% salicylic acid versus 30% salicylic acid with and without combination with doxycycline in the treatment of moderate acne vulgaris: a double-blinded, randomized, clinical trial

Public title

Salicylic acid in acne vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Moderate acne vulgaris(according to Vaishampayan classification) Age greater than 12 years

Exclusion criteria:

Pregnancy or intending to Breastfeeding Taking oral and topical acne medications in the last 34 day History of allergies to the drugs used in the study History of light sensitivity Existence of recurrent herpes simplex infection Presence of warts on the face and contagious molluscum in patients Active dermatitis on the face Having gastrointestinal disorders (especially esophagitis and gastroesophageal reflux) History of liver and kidney diseases

Age

From **12 years** old to **40 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, people who have the Word criterion to study, after obtaining the consent of the company to study based on the selected goal, then people will be divided into three groups of intervention 1, 2 and control in the form of glass permutation blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients and analysts will be unaware of the allocation of individuals to treatment groups. Prior to sampling, participants will be asked not to confuse the treatment method with other people, and also to note the treatment for individuals so that the samples have the least contact with each other.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Gonabad University of Medical Sciences

Street address

Khorasan Razavi, Gonabad, Imam Khomeini St., Gonabad University of Medical Sciences

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2021-02-06, 1399/11/18

Ethics committee reference number

IR.GMU.REC.1399.114

Health conditions studied**1****Description of health condition studied**

Acne vulgaris

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

acne vulgaris

Timepoint

Observation of the number and type of facial acne vulgaris before the intervention and 12 weeks after the intervention and also one month after the intervention

Method of measurement

system Vaishampayan, Standard Photography, Michelson Acne Score

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Intervention group: Patients are first examined by a dermatologist to measure the severity of

their acne based on Michelson's acne score, and patients undergo standard photography. Then (recipients of 30% salicylic acid and doxycycline) treatment for 12 weeks with doxycycline 100 mg daily and peeling 30% salicylic acid will be done every two weeks. Then, once every two weeks until the end of treatment and also one month after the end of treatment, acne severity will be assessed based on Michelson's acne score, patient satisfaction, improvement based on the doctor's opinion and examination based on photography.

Category

Treatment - Drugs

2

Description

Patients are first examined by a dermatologist to measure the severity of their acne based on Michelson's acne score, and patients undergo standard photography. Then (recipients of 40% salicylic acid and doxycycline placebo) treatment for 12 weeks with daily doxycycline placebo and 40% salicylic acid peeling will be performed every two weeks. Then, once every two weeks until the end of treatment and also one month after the end of treatment, acne severity will be assessed based on Michelson's acne score, patient satisfaction, improvement based on the doctor's opinion and examination based on photography.

Category

Treatment - Drugs

3

Description

Control group: Control group: At first, patients are examined by a dermatologist. The severity of their acne is measured based on Michelson's acne score and patients undergo standard photography. Then (recipients of 30% salicylic acid and doxycycline placebo) treatment for 12 weeks with doxycycline placebo Daily and 30% salicylic acid peeling will do once every two weeks. Then, once every two weeks until the end of treatment and also one month after the end of treatment, acne severity will be assessed based on Michelson's acne score, patient satisfaction, improvement based on the doctor's opinion and examination based on photography.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh bohlool hospital

Full name of responsible person

Hamideh Mohammadzadeh

Street address

Bohlol Hospital, Parastar Boulevard, Gonabad Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Shahla Khosravan

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Hamideh Mohammadzadeh

Position

Assistant Professor

Latest degree

Specialist

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

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is 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 will be provided to researchers without names and details.

When the data will become available and for how long

After completing the design and printing of the article

To whom data/document is available

All researchers and pharmaceutical companies

Under which criteria data/document could be used

For similar research, the officials of pharmaceutical companies can access the results of the project by referring to the research vice chancellor of Gonabad University of Medical Sciences with the written consent of the vice chancellor for research.

From where data/document is obtainable

Vice Chancellor for Research, Gonabad University of Medical Sciences

What processes are involved for a request to access data/document

Researchers can access the results of the project by referring to the Vice Chancellor for Research of Gonabad University of Medical Sciences with the written consent of the Vice Chancellor for Research.

Comments