Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Behlool 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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abolfazl.mokhtari1997@gmail.com

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
۹۶۹۱۷۹۳۷۱۸
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

IPatients 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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Postal code

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

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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

Dermatology
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Person responsible for scientific inquiries

Contact
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Hamideh mohammadzadeh
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Latest degree
Specialist
Other areas of specialty/work
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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