Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of a topical serum containing cannabidiol and niacinamide as an adjunct to oral doxycycline compared with topical placebo on the change in the number of inflammatory acne lesions from baseline to the end of the treatment period in patients with moderate acne vulgaris: a randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Study aim
To evaluate the additive effect of a topical serum containing cannabidiol and niacinamide, compared with placebo, on the treatment of moderate acne vulgaris, specifically in reducing inflammation and sebum secretion and improving skin appearance.

Design
Randomized, placebo-controlled, two-arm parallel trial on 48 patients; permuted block randomization (block size 4) using Random Allocation Software.

Settings and conduct
Dermatology Department, Shiraz University of Medical Sciences. Both groups receive oral doxycycline; the serum is applied to clean, dry facial skin for 12 weeks without other anti-acne products. The placebo matches the active serum in appearance, odor, and consistency. Assessments at baseline and week 12.

Participants/Inclusion and exclusion criteria
Patients with moderate acne vulgaris who sign the informed consent form will be included.

Intervention groups
Intervention: oral doxycycline 100 mg daily plus topical serum containing cannabidiol, niacinamide, papain, and alpha-glucan oligosaccharide for 12 weeks. Control: oral doxycycline 100 mg daily plus identical-appearing placebo serum for 12 weeks.

Main outcome variables
Change in the number of inflammatory acne lesions (papules and pustules) from baseline to the end of treatment; change in the number of non-inflammatory lesions; change in overall acne severity; change in sebum secretion; improvement in skin appearance; incidence of adverse effects; change in patients' quality of life (Cardiff Acne Disability Index)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260924071175N1**
Registration date: **2026-10-02, 1405/07/10**
Registration timing: **prospective**

Last update: **2026-10-02, 1405/07/10**
Update count: **0**

Registration date
2026-10-02, 1405/07/10

Registrant information

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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-10-23, 1405/08/01
Expected recruitment end date
2027-03-20, 1405/12/29
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of a topical serum containing cannabidiol and niacinamide as an adjunct to oral doxycycline compared with topical placebo on the change in the number of inflammatory acne lesions from baseline to the end of the treatment period in patients with moderate acne vulgaris: a randomized, double-blind, placebo-controlled clinical trial

Public title

Comparison of a Topical Cannabidiol and Niacinamide Serum Plus Oral Doxycycline With Placebo Plus Oral Doxycycline for the Treatment of Moderate Acne Vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 40 yearst Clinical diagnosis of facial acne vulgaris by a dermatologist Moderate acne defined as a Global Acne Grading System (GAGS) score of 19 to 30 Eligible for treatment with oral doxycycline according to the dermatologis Willingness to avoid any other topical or systemic anti-acne product during the study Signing the written informed consent form

Exclusion criteria:

Pregnancy, breastfeeding, or planning pregnancy Known hypersensitivity to tetracyclines Known hypersensitivity to cannabis products, niacinamide, papain, papaya, or any component of the serum Use of oral isotretinoin within the past 6 months use of oral antibiotics within the past 4 weeks Use of topical anti-acne medications within the past 2 weeks Starting or changing hormonal therapy (oral contraceptives, spironolactone) within the past 3 months Chemical peeling, laser, or other facial cosmetic procedures within the past 4 weeks Severe nodulocystic acne, acne conglobata, or acne fulminans Drug-induced acne or acne secondary to known endocrine disorders Other facial skin diseases such as rosacea, seborrheic dermatitis, or perioral dermatitis Known hepatic or renal disease Use of drugs with significant interaction with doxycycline, such as warfarin or systemic retinoids

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be individually randomized to the intervention or placebo group in a 1:1 ratio using permuted block randomization with a fixed block size of 4. No stratification will be applied. The random allocation sequence of 48 assignments (12 blocks of 4) will be generated with Random Allocation Software by a person independent of the research team who is not involved in recruitment, treatment, or outcome assessment. To conceal allocation, each assignment will be placed in a sequentially numbered, opaque, sealed envelope. Envelopes will be opened in order only after the participant has been enrolled and baseline assessments have been completed. The first author (Mohsen Olov) will enroll participants, and assignment to groups will be carried out by Dr. Mojdeh Sepaskhah according to the sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind trial. Participants and the outcome assessor (the dermatologist who counts lesions and determines GAGS scores) will be blinded to group allocation. The active serum and the placebo serum (water-based vehicle containing a viscosity-enhancing agent, a preservative, and fragrance, without any active ingredient) will be supplied by the manufacturer in identical containers with the same appearance, color, odor, and consistency, labeled only with codes. The allocation code list will be kept by a person outside the research team and will not be revealed until the end of data analysis, except in case of a serious adverse event requiring unblinding. The statistician will also analyze the data using coded groups.

Placebo

Used

Assignment

Parallel

Other design features

This is a single-center, add-on, placebo-controlled trial conducted at the Dermatology Department of Shiraz University of Medical Sciences. Both groups will receive oral doxycycline 100 mg once daily as standard treatment for moderate acne. In addition, the intervention group will apply a thin layer of a water-based serum containing cannabidiol, niacinamide, papain, and alpha-glucan oligosaccharide to the whole face, and the control group will apply an identical placebo serum in the same way, for 12 weeks. Participants will be instructed to apply the serum to clean, dry skin and to avoid any other anti-acne products. Outcomes will be assessed at baseline and after 12 weeks of treatment. Both the active and placebo serums are supplied free of charge by Persian Pod company.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of School of Medicine - Shiraz University of Medical Sciences
Street address
School of Medicine, Shiraz University of Medical Sciences, Imam Hossein Square, Zand Street
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Approval date
2026-08-25, 1405/06/03

Ethics committee reference number
IR.SUMS.MED.REC.1405.241

Health conditions studied

1

Description of health condition studied
Moderate acne vulgaris

ICD-10 code
L70.0

ICD-10 code description
Acne vulgaris

Primary outcomes

1

Description
Number of inflammatory acne lesions (papules and pustules)

Timepoint
At baseline (before intervention) and 12 weeks after the start of treatment

Method of measurement
Clinical counting of lesions by a dermatologist

Secondary outcomes

1

Description
: Number of non-inflammatory acne lesions (open and closed comedones)

Timepoint
At baseline (before intervention) and 12 weeks after the start of treatment

Method of measurement
Clinical counting of lesions in specified facial areas by a dermatologist

2

Description

Timepoint

Method of measurement

3

Description
Overall acne severity score

Timepoint
At baseline (before intervention) and 12 weeks after the start of treatment

Method of measurement
Global Acne Grading System assessed by a dermatologist

4

Description
Incidence of adverse effects (itching, skin redness, worsening of lesions, irritation)

Timepoint
During the 12-week treatment period and at 12 weeks after the start of treatment

Method of measurement
Physical examination and history taking by a dermatologist

5

Description
Quality of life score of patients

Timepoint
At baseline (before intervention) and 12 weeks after the start of treatment

Method of measurement
Cardiff Acne Disability Index questionnaire (score 0 to 15)

Intervention groups

1

Description
Intervention group: Oral doxycycline 100 mg capsule once daily, taken with at least one large glass of water, without lying down for half an hour afterward, and not with dairy products or calcium-containing supplements, plus 3 to 4 drops of a water-based topical serum containing cannabidiol, niacinamide, papain (a proteolytic enzyme), and alpha-glucan oligosaccharide (a prebiotic) applied as a thin layer to the whole face on clean, dry skin twice daily (morning and night) for 12 weeks. Other anti-acne products are not allowed during the study. The serum is manufactured and supplied free of charge by Persian Pod company. Ingredient concentrations have not been disclosed by the manufacturer for confidentiality reasons.

Category
Treatment - Drugs

2

Description
Control group: Oral doxycycline 100 mg capsule once daily with the same instructions as the intervention group, plus 3 to 4 drops of a placebo serum applied as a thin layer to the whole face on clean, dry skin twice daily

(morning and night) for 12 weeks. The placebo serum is water-based and contains only a viscosity-enhancing agent, a preservative, and fragrance, without any active ingredient, and is identical to the active serum in appearance, color, odor, consistency, and packaging. Other anti-acne products are not allowed during the study. The placebo is manufactured and supplied free of charge by Persian Pod company.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dermatology Clinic, Shahid Faghihi Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Shiraz 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
Shiraz University of Medical Sciences
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Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available