Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of topical N Acetylcystein%5 on mild to moderate Acne Vulgaris: a double blind randomized clinical trial

Protocol summary

Study aim

This study was designed to determine the effect of topical 5% N-acetylcysteine gel compared to placebo on the treatment and quality of life of patients with mild to moderate acne vulgaris.

Design

This study will be conducted as a randomized, double-blind, phase 3, parallel-group clinical trial involving 146 patients with mild to moderate acne vulgaris referred to Farschian Hospital in Hamadan. Patients will be divided into two groups and will be treated for 8 weeks. The rand function of Excel software was used for randomization.

Settings and conduct

The study will be conducted at Farshchian Hospital (Skin department) in Hamadan on patients with mild to moderate acne vulgaris to determine the effect of topical 5% L-N-acetylcysteine on acne. The study is double-blind. The patient and the person assessing the outcome of the treatment will be unaware of the groups.

Participants/Inclusion and exclusion criteria

Participants were patients with mild to moderate acne vulgaris on the face. Inclusion criteria were age 12 to 30 years, number of inflammatory and non-inflammatory lesions between 20 and 100, and no use of topical or oral acne treatments in the past 3 months. Exclusion criteria included: having underlying medical conditions such as diabetes or thyroid disorders, being pregnant or breastfeeding, having a history of refractory acne, and having other types of acne (such as acne conglobata).

Intervention groups

One group of patients will receive topical N-acetylcysteine 5% gel plus topical clindamycin for 8 weeks. The other group will receive topical clindamycin plus placebo (base gel without N-acetylcysteine).

Main outcome variables

Study outcomes included change in acne lesion count based on the Global Acne Grading System (GAGS) index.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N48**
Registration date: **2025-10-07, 1404/07/15**
Registration timing: **prospective**

Last update: **2025-10-07, 1404/07/15**
Update count: **0**

Registration date

2025-10-07, 1404/07/15

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2026-01-20, 1404/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of topical N Acetylcystein%5 on mild to moderate Acne Vulgaris: a double blind randomized clinical trial

Public title
Acne Treatment with N-Acetylcysteine Gel

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with mild to moderate facial acne vulgaris Age 12–30 years Lesion count: 20–100 inflammatory/non-inflammatory lesions No systemic or topical acne treatments in the past 3 months

Exclusion criteria:
Pregnancy or lactation History of treatment-resistant acne. Other acne subtypes (e.g., conglobata) Having underlying medical conditions such as diabetes or thyroid disorders

Age
From **12 years** old to **30 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **146**

Randomization (investigator's opinion)
Randomized

Randomization description
The treatment allocation to the treatment and placebo groups will be done randomly. Using the method of four-way random blocks, patients will be divided into two groups: treatment and placebo. In this way, all the cases where, for example, two treatments A and B can be placed in four-way blocks will be considered and in the next step, the blocks will be selected using the table of random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
All gel tubes (both drug and placebo) are prepared in completely identical packaging without any recognizable identifiers by the Hamadan Faculty of Pharmacy. Each tube is coded A or B with no direct reference to the contents (NAC or placebo). A random assignment list is prepared by an independent person (skin assistant). This list is a confidential document that is disclosed at the end of the relevant code design. Therefore, the treating physician and the patient will be unaware of the contents inside the tubes (double-blind) and the relevant codes will be disclosed during the data analysis design.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hamadan Univercity of Medical Science

Street address
Shahid Fahmideh

City
Hamadan

Province
Hamadan

Postal code
6517838697

Approval date
2025-09-06, 1404/06/15

Ethics committee reference number
IR.UMSHA.REC.1404.454

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
Changes in acne severity

Timepoint
Before treatment, end of week 3, 6, and 8 after treatment

Method of measurement
Global Acne Grading System (GAGS)

Secondary outcomes

1

Description
Treatment complications

Timepoint
From the start of treatment to the end of the eighth week

Method of measurement
Questioning the patient

Intervention groups

1

Description
Intervention group: will be treated with topical 5% N-acetylcysteine gel and topical clindamycin.
Category
Treatment - Drugs

2

Description
Control group: They will receive placebo (base gel without N-acetylcysteine) along with topical clindamycin
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshcian Hospital (Sina)
Full name of responsible person
Bahareh Ebrahimi
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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
Hamedan 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
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Abbas Moradi
Position
Coach
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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
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
Yes - There is 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
Title and more details about the data/document
All data can be shared except for authors names
When the data will become available and for how long
From 2026 onwards it is permissible
To whom data/document is available
Clinical professionals and Researchers in all fields
Under which criteria data/document could be used
For treatment of patients and develop research and science
From where data/document is obtainable
Correspond to the email address of the scientific responsible for the study b.ebrahimi.4362@gmail.com
What processes are involved for a request to access data/document
Send and receive email
Comments