

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 randomization 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

Iran (Islamic Republic of)

Phone

+98 81 3838 0097

Email address

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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 University 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

Street address

Mirzadeh Eshghi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan 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

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

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

Coach

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Latest degree

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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

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