Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Effect of oral N-Acetylcysteine versus placebo on the severity of the clinical signs in patients with acne: a double-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of oral N-Acetylcysteine versus placebo on the severity of the clinical signs in patients with acne

Design
This is a double-blind randomized clinical trial, phase II, in which 90 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible patients with acne who will refer to Sina Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 15 to 65 years; Having acne
Exclusion criteria: Pregnancy; Using asteroid in the past three months; Diabetes; Hypercholesterolemia; Renal or liver failure

Intervention groups
Intervention group: Capsule Doxycycline 100 mg twice a day for 8 weeks and ointment Clindamycin 1% or Benzyl peroxide 5% twice a day for 8 weeks and tablet N-Acetylcysteine 600 mg twice a day for 8 weeks Control group: Capsule Doxycycline 100 mg twice a day for 8 weeks and ointment Clindamycin 1% or Benzyl peroxide 5% twice a day for 8 weeks and tablet placebo twice a day for 8 weeks

Main outcome variables
Primary outcome: Assessing the severity of clinical signs

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N226**
Registration date: **2018-07-01, 1397/04/10**
Registration timing: **prospective**
Last update: **2018-07-01, 1397/04/10**
Update count: **0**

Registration date
2018-07-01, 1397/04/10

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-06, 1397/04/15

Expected recruitment end date
2019-01-05, 1397/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of oral N-Acetylcysteine versus placebo on the severity of the clinical signs in patients with acne: a double-blind randomized clinical trial

Public title
Effect of oral N-Acetylcysteine versus placebo on the

severity of the clinical signs in patients with acne

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 15 to 65 years; Having acne

Exclusion criteria:

Pregnancy; Using asteroid in the past three months; Diabetes; Hypercholesterolemia; Renal or liver failure

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double-blind

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 Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

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Province

Hamadan

Postal code

6517838695

Approval date

2018-05-19, 1397/02/29

Ethics committee reference number

IR.UMSHA.REC.1397.095

Health conditions studied

1

Description of health condition studied

Acne

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

Assessing the severity of clinical signs

Timepoint

Before and 4 and 8 weeks after intervention

Method of measurement

Through physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Capsule Doxycycline 100 mg twice a day for 8 weeks and ointment Clindamycin 1% or Benzyl peroxide 5% twice a day for 8 weeks and tablet N-Acetylcysteine 600 mg twice a day for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Capsule Doxycycline 100 mg twice a day for 8 weeks and ointment Clindamycin 1% or Benzyl peroxide 5% twice a day for 8 weeks and tablet placebo twice a day for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person
Dr. Zhra Ahmadi
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Sina Hospital, Mirzadeh Eshghi Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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