

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Effect of brimonidine tartrate gel 0.33% versus tretinoin cream 0.05% on post-acne erythema: a single-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of brimonidine tartrate gel 0.33% versus tretinoin cream 0.05% on post-acne erythema

Design

This is a Phase III single-blind randomized clinical trial with a control group, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct

This study will be conducted at the Sina Hospital in Hamadan city, involving 90 eligible patients with Acne. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be single-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 70 years Erythema after acne
Exclusion criteria: Pregnancy or breastfeeding
Taking anti-acne drugs in the last 3 months
Contraindications to Brimonirin (including treatment failure, brain failure, depression, blood pressure, scleroderma, Sjogren's syndrome, Raynaud's phenomenon)

Intervention groups

Intervention group: Brimonidine tartrate gel 0.33% once a day topically at the site of acne erythema for 4 weeks
Control group: Tretinoin cream 0.05% once a day topically at the site of acne erythema for 4 weeks.

Main outcome variables

Primary outcome: Severity of post-acne erythema
Skin burning

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N490**

Registration date: **2023-11-19, 1402/08/28**

Registration timing: **prospective**

Last update: **2023-11-19, 1402/08/28**

Update count: **0**

Registration date

2023-11-19, 1402/08/28

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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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of brimonidine tartrate gel 0.33% versus tretinoin cream 0.05% on post-acne erythema: a single-blind randomized clinical trial

Public title

Effect of brimonidine tartrate gel 0.33% versus tretinoin cream 0.05% on post-acne erythema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 70 years Erythema after acne

Exclusion criteria:
Pregnancy or breastfeeding Taking anti-acne drugs in the last 3 months Contraindications to Brimonirin (including treatment failure, brain failure, depression, blood pressure, scleroderma, Sjogren's syndrome, Raynaud's phenomenon)

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

Blinding (investigator's opinion)
Single blinded

Blinding description
The form of the drugs is completely the same, so that patients do not know which gel or cream is brimonidine or tretinoin. Consequently, patients will remain unaware of the type of intervention they receive. Therefore, the trial will be conducted as a single-blind study.

Placebo
Not 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, Fahmideh
Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2023-11-04, 1402/08/13

Ethics committee reference number

IR.UMSHA.REC.1402.510

Health conditions studied

1

Description of health condition studied

Acne

ICD-10 code

L70

ICD-10 code description

Acne

Primary outcomes

1

Description

Severity of post-acne erythema

Timepoint

Before the intervention and in the fourth and eighth weeks after the intervention

Method of measurement

By clinical examination

Secondary outcomes

1

Description

Skin burning

Timepoint

In the fourth and eighth weeks after the intervention

Method of measurement

By taking a history

Intervention groups

1

Description

Intervention group: Brimonidine tartrate gel 0.33% once a day topically at the site of acne erythema for 4 weeks

Category

Treatment - Drugs

2

Description

Control group: Tretinoin cream 0.05% once a day topically at the site of acne erythema for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital in Hamadan city

Full name of responsible person

Dr Roshanak Kazemirad

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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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

Dr Roshanak Kazemirad

Position

Resident of Dermatology

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

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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