

# 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)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### 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.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3827 4184

**Email**

Karadr26@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Reza Shokoohi

**Street address**

Hamadan University of Medical Sciences, Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0717

**Email**

info.research@umsha.ac.ir

**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

**Street address**

School of Medicine, Hamadan University of Medical Sciences, Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

Karadr26@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Jamshidi

**Position**

Dermatologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

School of Medicine, Hamadan University of Medical Sciences, Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

jamshidim84@yahoo.com

## 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**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

School of Public Health, Hamadan University of  
Medical Sciences, Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

### Email

poorolajal@umsha.ac.ir

## 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