Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of Brimonidine 0.33% gel and placebo on the clinical erythema score in post-acne erythema patients

Protocol summary

Study aim
Comparison of the efficacy of brimonidine 0.33% gel and placebo in the treatment of post-acne erythema

Design
Phase 3, parallel group, clinical trial, with consecutive sampling, including 30 patients, double blinded, computerized randomized with permuted blocks

Settings and conduct
The study is conducted in the dermatology clinic of Shiraz University of Medical Sciences. Group 1 will apply Brimonidine 0.33% gel once overnight on the face. Group two will apply Lubricant gel once overnight on the face. The patients are assessed at the beginning of treatment, 4th week, and 8th week of treatment and one month after cessation of treatment Visioface photography. The patients and outcome assessor are blinded to the type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients between 18 and 45 years of age with post-acne erythema after successful treatment of acne vulgaris Exclusion criteria: pregnancy, lactation, depression, cerebral or coronary artery insufficiency, severe or unstable cardiovascular disease

Intervention groups
Intervention group: Brimonidine 0.33% gel (Janus, Tehran, Iran) is applied once overnight on the face. Control group: Lubricant gel (Razak, Tehran, Iran) is applied once overnight on the face.

Main outcome variables
Clinician score of post-acne erythema

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140212016557N11**
Registration date: **2023-07-31, 1402/05/09**
Registration timing: **prospective**
Last update: **2023-07-31, 1402/05/09**
Update count: **0**

Registration date
2023-07-31, 1402/05/09

Registrant information

Name
Mozhdeh Sepaskhah

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 712125239

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sepaskhah@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2024-03-19, 1402/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Brimonidine 0.33% gel and placebo on the clinical erythema score in post-acne erythema patients

Public title
Assessing the effect of brimonidine gel on the redness remained after pimples

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between 18 and 45 years of age Post-acne erythema after successful treatment of acne vulgaris

Exclusion criteria:

pregnancy lactation depression cerebral or coronary artery insufficiency Raynaud’s phenomenon orthostatic hypotension thromboangiitis obliterans scleroderma Sjögren’s syndrome severe or unstable cardiovascular disease

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are recruited by consecutive sampling in the study. Randomization is performed by random allocation software and participants are randomly allocated in the intervention or control group. Randomization of 30 participants in the software is performed by randomization blocks size 4 with random ratio of 1:1. The output of the software is a table that shows the number of each participant is allocated in the intervention or control group. The medications are in the similar containers labeled by numbers of the patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

All drugs are packed in similar containers and have similar color, smell, and texture; and, the containers allocated to each patient are labelled with the same patients of patient recruitment number. Care provider and investigator that deliver the gels are not involved in the outcome assessment. The outcome assessor is not aware of the type of drugs in each patient. Due to similarity of the drugs and the instructions, the patients are also unaware of the type of used drugs. Therefore the research will be double-blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of MedicalSscience, zand Ave.

City

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Province

Fars

Postal code

71348-14336

Approval date

2023-04-30, 1402/02/10

Ethics committee reference number

IR.SUMS.MED.REC.1402.052

Health conditions studied

1

Description of health condition studied

Post-acne erythema

ICD-10 code

L70.8

ICD-10 code description

Other acne

Primary outcomes

1

Description

Clinician score of post-acne erythema

Timepoint

Before intervention, 4 and 8 weeks after starting intervention, and 1 months after treatment cessation

Method of measurement

5-point clinical score, defined as: 0=clear with no erythema, 1 = almost clear or slight redness, 2 = mild or definite redness, 3 = moderate or marked redness, 4 = severe or fiery redness

Secondary outcomes

1

Description

Skin erythema index

Timepoint

Before intervention, 4 and 8 weeks after starting intervention, and 1 months after treatment cessation

Method of measurement

Dermacatch instrument

2

Description

Patient self-assessment of post acne erythema treatment

Timepoint

4 and 8 weeks after starting intervention, and 1 months after treatment cessation

Method of measurement

4-point patient assessment of treatment result expressedas: a. No improvement, b. Mild improvement, c. Good improvement, d. Excellent improvement

3

Description

Quality of life

Timepoint

before intervention and 1 months after cessation of treatment

Method of measurement

Dermatology Life Quality index questionnaire Persian version

Intervention groups

1

Description

Intervention group: Brimonidine 0.33% gel (Janus, Tehran, Iran) is applied once overnight on the face.

Category

Treatment - Drugs

2

Description

Control group: Lubricant gel (Razak, Tehran, Iran) is applied once overnight on the face.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic, Shahid Faghihi hospital

Full name of responsible person

Mozhdeh Sepaskhah

Street address

Dermatology clinic, Faghihi hospital, Zand St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Research Council, Shiraz University of Medical Sciences, Zand St., Shiraz, Iran

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Grant name

Research grant of the Research Council of Shiraz University of Medical Sciences

Grant code / Reference number

25880

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mozhdeh Sepaskhah

Position

Associate prefessor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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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
No - There is not 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
No - There is not 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