

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Safety and efficacy assessment of Brimonidine topical formulation on rosacea disease

Protocol summary

Study aim

evaluation of clinical efficacy of topical formulation of Brimonidine on Rosacea disease

Design

Phase II single group. before -after, clinical study

Settings and conduct

This interventional study is performed as a before-after clinical trial in Center for Education and Research of Dermatology and Leprosy, Tehran University of Medical Sciences. A total of 20 patients with rosacea referring to dermatology clinic in Tehran in the year 1395 who want to participate in the study and complete the consent form are entered in the study. They receive topical gel brimonidine 0.5 once daily for 8 weeks. The rate of healing is evaluated 4 and 8 weeks after treatment; more over the observed side-effects are recorded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with acne rosacea who have not received treatment in the last three months. Men and women over 18 years, clinical diagnosis of facial rosacea score 4 based on Patient Self-Assessment (PSA) or score ≥ 3 based on Clinician Erythema Assessment (CEA).
Exclusion Criteria: severe side-effects and hypersensitivity to brimonidine, those who have more than 5 inflammatory lesions (papule or pustule), Particular forms of rosacea (rosacea conglobata, rosacea fulminans, isolated rhinophyma, isolated pustulosis of the chin) or other concomitant facial dermatoses that are similar to rosacea such as peri-oral dermatitis, demodicidosis, facial keratosis pilaris, seborrheic dermatitis, acute lupus erythematosus, or actinic telangiectasia, Previous treatment with Brimonidine gel 33% or any other Brimonidine Tartarate formulated treatment on rosacea erythema four weeks before entering the study.

Intervention groups

Intervention group: patients with Acne Rosacea who receive Brimonidine topical gel twice a day for 8 weeks

Main outcome variables

Significant improvement in severity of lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161207031288N4**

Registration date: **2019-01-27, 1397/11/07**

Registration timing: **retrospective**

Last update: **2019-01-27, 1397/11/07**

Update count: **0**

Registration date

2019-01-27, 1397/11/07

Registrant information

Name

Saman Ahmad Nasrollahi

Name of organization / entity

Center for Research and Training in Skin Diseases and Leprosy Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 8190

Email address

snasrollahi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

2017-10-15, 1396/07/23

Actual recruitment end date

2018-02-21, 1396/12/02
Trial completion date
2018-05-30, 1397/03/09

Scientific title
Safety and efficacy assessment of Brimonidine topical formulation on rosacea disease

Public title
Effect of Brimonidine on rosacea disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having rosacea disease No treatment received in last three months
Exclusion criteria:
More than 5 inflammatory acne lesions Special forms of rosacea in addition to Dermatitis Acute Lupus erythematosus Previous treatment with Brimonidine gel 33% Seborrheic dermatitis

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **20**
Actual sample size reached: **20**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Research and Technology Dept, 6th floor, Central Organization of the University, Ghods St., Keshavarz Blvd.
City
Tehran

Province
Tehran
Postal code
1417653761
Approval date
2017-04-15, 1396/01/26
Ethics committee reference number
IR.TUMS.VCR.REC.1396.2072

Health conditions studied

1

Description of health condition studied
Rosacea
ICD-10 code
L71
ICD-10 code description
Rosacea

Primary outcomes

1

Description
severity of lesions according to and Clinician Erythema Assessment (CEA)
Timepoint
Before treatment and 4 and 8 weeks later
Method of measurement
Physical exam

Secondary outcomes

1

Description
Severity of lesions according to Patient Self-Assessment (PSA)
Timepoint
Before treatment and 4 and 8 weeks later
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Brimonidine topical gel twice a day for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
The Pharmaceutical, Cosmeceutical and Hygienic Skin

Products Clinical Evaluation Unit (DermaLab) cen

Full name of responsible person

Aniseh Samadi

Street address

No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.

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Fax

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dermalab@tums.ac.ir

Web page address

http://crtSDL.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jarfandishan-e Navid-e Salamat (Janus) knowledge-based Company

Full name of responsible person

Najva Kashani

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No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.

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Headoffice@Januspharma.com

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Jarfandishan-e Navid-e Salamat (Janus) knowledge-based Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

Supervisor of clinical study unit

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooz

Position

Professor of dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Clinical Research

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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

Undecided - It is not yet known if there will be 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