

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

preparation and clinical evaluation of combination of ivermectin and brimonidine topical formulation for treatment of rosacea

Protocol summary

Study aim

evaluation of clinical efficacy of topical formulation of Brimonidine and Ivermectin 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 15 patients with rosacea referring to dermatology clinic in Tehran in the year 1399 who want to participate in the study and complete the consent form are entered in the study. They receive topical cream brimonidine 0.5% /Ivermectin 1% 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/Ivermectin, 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.

Intervention groups

Intervention group: consumption of Brimonidine/ivermectin topical cream once a day for 8 weeks

Main outcome variables

severity of lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161207031288N7**

Registration date: **2021-01-31, 1399/11/12**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-31, 1399/11/12**

Update count: **0**

Registration date

2021-01-31, 1399/11/12

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

2020-11-21, 1399/09/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

preparation and clinical evaluation of combination of ivermectin and brimonidine topical formulation for treatment of rosacea

Public title

effect of ivermectin and brimonidine combination in rosacea

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having rosacea disease treatment received in last three months men and women over 18 years

Exclusion criteria:

More than 5 inflammatory acne lesions Special forms of rosacea in addition to Dermatitis Seborrheic dermatitis Acute lupus erythematosus demodicosis actinic telangiectasia Hypersensitivity to brimonidine/Ivermectin

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **15**

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 Islamic Azad Tehran Medical Sciences University_Pharmacy and Pharmaceutical of p

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1419943471

Approval date

2020-10-13, 1399/07/22

Ethics committee reference number

IR.IAU.PS.REC.1399.218

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/Ivermectin topical cream twice a day for 8 weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Center For Research And Training In Skin Diseases And Leprosy

Full name of responsible person

Saman Ahmad Nasrollahi

Street address

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

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Web page address

http://crtSDL.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Center For Research and Training in skin Diseases and Leprosy

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

Center For Research And Training In Skin Diseases And Leprosy

Full name of responsible person

Saman Ahmad Nasrollahi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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

Proffesor 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

Islamic Azad University

Full name of responsible person

Samin Fallah Pakdaman

Position

Pharmacy Student

Latest degree

Master

Other areas of specialty/work

Medical Pharmacy

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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