

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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  $\geq 3$  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

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##### 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  
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No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.  
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## Sponsors / Funding sources

### 1

#### Sponsor

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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  
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Associate professor  
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Medical Pharmacy  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
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## Person responsible for updating data

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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