Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ivermevectin 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 Dermatosis Seborrheic dermatits 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.
City
tehran
Province
Tehran
Postal code
1416613675
Phone
+98 21 8897 2220
Email
samannasrol@gmail.com
Web page address
http://crtsdl.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Center For Research and Training in skin Diseases and Leprosy
Full name of responsible person
Saman Ahmad Nasrollahi
Street address
No. 415, Taleghani Ave.,Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1416613675
Phone
+98 21 8897 2220
Email
samannasrol@gmail.com
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
Street address
No. 415, Taleqani Ave., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1416613675
Phone
+98 21 8896 0880
Email
snasrollahi@tums.ac.ir

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
Street address
No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.
City
Tehran
Province
Tehran
Postal code
1416613675
Phone
+98 21 8897 7921
Email
firozali@sina.tums.ac.ir

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

Street address

Yakhchal street _Gholhak _ Dr.Shariati avenue

City

Tehran

Province

Tehran

Postal code

1941933111

Phone

+98 21 2264 0051

Email

fallahpsamin@yahoo.com

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