Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the efficacy of cyclosporine cream 5% compared to metronidazole gel 0/75% in the treatment of rosacea: A randomized controlled clinical trial

Protocol summary

Study aim
Determination of the efficacy of cyclosporine cream compared with metronidazole gel in the treatment of rosacea

Design
A controlled, parallel, single-blinded, randomized, phase 2-3 clinical trial of 60 patients. Randomized with sealed envelopes.

Settings and conduct
In all patients, after collecting demographic and clinical data, the face is photographed and each patient is randomly assigned to one of the two groups mentioned above. The treatment period is three months, and the evaluation of the study results is performed by a dermatologist who blindly assesses the type of intervention after one, two, three, and five months after the start of treatment. Data analysis is also performed by a blinded statistician.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients 15 to 50 years of age with a confirmed diagnosis of erythematotelangiectatic or papulopustular rosacea or a combination of both, the patient has not received treatment for their condition in the past two months, no serious underlying disease
Exclusion criteria: Occurrence of allergy or bacterial or viral disease during treatment or follow-up period

Intervention groups
1. Treatment with metronidazole gel 0.75% once per night 2. Treatment with 5% cyclosporine cream once per night

Main outcome variables
Evaluating the severity of the disease with the total severity score of rosacea

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190901044666N2**
Registration date: **2022-12-05, 1401/09/14**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-05, 1401/09/14**
Update count: **0**

Registration date
2022-12-05, 1401/09/14

Registrant information

Name
Afsaneh Sadeghzadeh bazargan

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6435 2421

Email address
sadeghzadeh.a@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-26, 1401/09/05

Expected recruitment end date
2023-05-21, 1402/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of cyclosporine cream 5%

compared to metronidazole gel 0/75% in the treatment of rosacea: A randomized controlled clinical trial

Public title
The effect of cyclosporine cream on rosacea
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 15 to 50 years Patients with a confirmed diagnosis of erythematotelangiectatic or papulopustular rosacea or a combination of both The patient has not received treatment for his or her disease in the past two months Absence of a serious underlying disease Patient's cooperation in the implementation of therapeutic measures and participation in all therapeutic sessions
Exclusion criteria:
The occurrence of a sensitivity or adverse reaction to any of the therapeutic agents that prevents continuation of treatment The occurrence of bacterial or viral skin disease during treatment or the follow-up period
Age
From **15 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
After being selected by available method, patients are divided into two groups by simple randomization, so that among 60 sealed bags, one bag will be randomly selected for each patient. Each bag contains the letter a or b: a for metronidazole gel and b for cyclosporine cream
Blinding (investigator's opinion)
Single blinded
Blinding description
The evaluation of the study results is performed by an evaluator blinded to the type of intervention (a dermatologist who does not know which treatment group the patient belongs to) and based on the images of the lesions taken in each session. Data analysis is also performed by a blinded statistician.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences, School of Medicine
Street address
School of Medicine, Iran University of Medical Sciences, Hemmat Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2022-11-15, 1401/08/24
Ethics committee reference number
IR.IUMS.FMD.REC.1401.431

Health conditions studied

1

Description of health condition studied
Erythematotelangiectatic or papulopustular rosacea
ICD-10 code
L71
ICD-10 code description
Rosacea

Primary outcomes

1

Description
Evaluating the severity of the disease
Timepoint
One, two, three and five months after starting treatment
Method of measurement
By the total severity score of rosacea

Secondary outcomes

1

Description
Doctor and patient satisfaction
Timepoint
One, two, three and five months after starting treatment
Method of measurement
Caregiver treatment satisfaction (CTS) questionnaire scale

2

Description
safety
Timepoint

One, two, three and five months after starting treatment

Method of measurement

Examining the side effects of the treatment with a questionnaire

3

Description

tolerability

Timepoint

One, two, three and five months after starting treatment

Method of measurement

with the Investigator Assessment of Tolerability scale

Intervention groups

1

Description

Intervention group 1: Treatment with metronidazole gel 0.75% once per night for 3 months. For this purpose, the patient uses a thin layer of metronidazole gel locally on his/her erythematotelangiectatic or papulopustular lesions.

Category

Treatment - Drugs

2

Description

Intervention group 2: Treatment with cyclosporine cream 5% once a night for 3 months. For this purpose, the patient uses a thin layer of cyclosporine cream locally on his/her erythematotelangiectatic or papulopustular lesions.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram hospital

Full name of responsible person

Afsaneh Sadeghzadeh Bazargan

Street address

Rasool Akram hospital, Niayesh avenue, Sattarkhan street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2391

Email

sadeghzadeh.a@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hosein Keyvani

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

keyvani.h@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Afsaneh Sadeghzadeh bazargan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Rasool Akram Hospital, Niayesh St, Satarkhan Av, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2421

Fax

Email

sadeghzadeh.a@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Afsaneh Sadeghzadeh bazargan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Rasool Akram Hospital, Niayesh St, Satarkhan Av, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2421

Fax

Email

sadeghzadeh.a@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Fatemeh beheshti

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Dermatology ward, Rasool Akram hospital, Mansoori avenue, Sattarkhan street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2390

Email

fatemebe64@gmail.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

Not applicable