

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of Efficacy Permethrin 5% Cream with Ivermectin 1% Cream in Combination with Oral Doxycycline in Treatment of Papulopustular Rosacea Patients

Protocol summary

Study aim

Comparison of Efficacy Between Permethrin 5% Cream and Ivermectin 1% Cream in Combination with Oral Doxycycline in Treatment of Papulopustular Rosacea Patients

Design

Clinical trial has 2 groups of 20 people and parallel, double blind, randomized, phase 3 on 40 patients. For randomization is used from statistic software

Settings and conduct

The Papulopustular Rosacea patients is photographed before and after treatment by Permethrin cream 5% or Ivermectin cream 1% in Alzahra Hospital. Patients and consequence evaluator are blinded in this study

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Diagnosis of typical papulopustular rosacea according to two dermatologists and performance biopsy if rosacea is suspected 2-No treatment with topical steroids or other topical treatment during 14 days before starting study 3-No treatment with any systemic drugs by known effect on inflammation responses during 30 days before starting study 4-No treatment with topical retinoids during 30 days ago or systemic retinoids during 180 days before starting study 5-No treatment by physical modality that effect on rosacea lesions during 30 days before starting study 6-Absence of other cutaneous diseases that interfere with assessment lesions related to rosacea 7-Absence of comedon, cyst and scar that benefit to diagnosis of acne vulgaris 8-Absence of pregnancy and breastfeeding Exclusion criteria: 1-Less than 18 years 2-Male gender

Intervention groups

Comparison of Efficacy Between Permethrin 5% Cream in one group of 20 people and Ivermectin 1% Cream in Combination with Oral Doxycycline in one group of 20 people in Treatment of Papulopustular Rosacea Patients. Any body of groups should papulopustular

rosacea individuals over 18 years

Main outcome variables

Increase or decrease number and severity after use Ivermectin 1% cream or permethrin 5% cream

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210729052010N1**

Registration date: **2021-12-24, 1400/10/03**

Registration timing: **prospective**

Last update: **2021-12-24, 1400/10/03**

Update count: **0**

Registration date

2021-12-24, 1400/10/03

Registrant information

Name

Mohammaddavood Zomorodian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3236 8244

Email address

zomorodianmd@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Efficacy Permethrin 5% Cream with Ivermectin 1% Cream in Combination with Oral Doxycycline in Treatment of Papulopustular Rosacea Patients

Public title
Comparison of Efficacy Permethrin topical Cream in Combination with Doxycycline Tablet with Ivermectin topical Cream in Combination with Doxycycline Tablet in Treatment of cutaneous disease Rosacea Patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of typical papulopustular rosacea according two dermatologists and performance biopsy if rosacea is suspected No treatment with topical steroids or other topical treatment during 14 days before starting study No treatment with any systemic drugs by known effect on inflammation responses during 30 days before starting study No treatment with topical retinoids during 30 days ago or systemic retinoids during 180 days before starting study No treatment by physical modality that effect on rosacea lesions during 30 days before starting study Absence of other cutaneous diseases that interfere with assessment lesions related to rosacea Absence of comedon, cyst and scar that benefit to diagnosis of acne vulgaris Absence of pregnancy and breastfeeding

Exclusion criteria:

Less than 18 years Male gender

Age
From **18 years** old

Gender
Female

Phase
3

- Groups that have been masked**
- Participant
 - Investigator
 - Data and Safety Monitoring Board

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
For Randomization is used from table of random numbers.in this study there is two treatment groups(treatment by permethrin 5% cream=A and treatment by Ivermectin 1% cream=B).every odd number an assignment to A and every even number an assignment to B.we close our eyes and put a finger anywhere on the table and write the column and row number that will our starting point and also write the direction we will move in the table from starting point

horizontally to the left.then we will write assigned treatment by intended randomized number and when the first patient will enroll,the first assigned treatment will be done and second treatment for second patient and so on.when the number of group A or B patients completed,we forced assign the rest of number of patients to notcompletedgroup.although it is possible to create equal vigesimal groups that in this case does not need to do above way. in this way ,treatment assignment for next patient is not predictable.In this study the patients have equal chance for selection in one of two intervention groups.In this study we don't use from stratified randomization for example patients of case study don't grouping based on sex and age and other factors.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Drugs is delivered by pharmacist in similar tubes but coded tube without information of the treating physician and patients from the type of drugs

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Soffe Ave., Alzahra Hospital

City

Isfahan

Province

Isfahan

Postal code

8174675731

Approval date

2020-09-04, 1399/06/14

Ethics committee reference number

IR.MUI.MED.REC.1399.456

Health conditions studied

1

Description of health condition studied

Rosacea papulopustular disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Increase or decrease number and severity after use Ivermectin 1% cream or permethrin 5% cream

Timepoint

0,6 and 12 weeks after starting treatment

Method of measurement

Photography from lesions and remission of lesions

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group:use of permethrin 5% topical cream produced by Gilan daroo company for 12 weeks on cutaneous lesions for 20 papulopustular rosacea patients and photography from their cutaneous lesions in 0 and 6 and 12 weeks after treatment and compare photos together

Category

Treatment - Drugs

2

Description

second Intervention group:use of Ivermectin 1% topical cream produced by Gilan daroo company for 12 weeks on cutaneous lesions for 20 papulopustular rosacea patients and photography from their cutaneous lesions in 0 and 6 and 12 weeks after treatment and compare photos together

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Nazila Poostiyan

Street address

Soffe Ave., Alzahra Hospital

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Nazila Poostiyan

Street address

Soffe Ave., Alzahra Hospital

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

Alzahra@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Nazila Poostiyan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Soffe Ave., Alzahra Hospital

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

Alzahra@mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Nazila Poostiyan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Soffe Ave., Alzahra Hospital

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

Alzahra@mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Nazila Poostiyan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Soffe Ave., Alzahra Hospital

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

Alzahra@mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Comparison of Efficacy Between Permethrin 5% Cream and Ivermectin 1% Cream in Combination with Oral Doxycycline in Treatment of Papulopustular Rosacea Patients

When the data will become available and for how long

It will be published as soon as the research project is completed

To whom data/document is available

Every body

Under which criteria data/document could be used

In order to inform and under any circumstances

From where data/document is obtainable

To the site

What processes are involved for a request to access data/document

It have not special process

Comments