Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 Permetrin cream5% or Ivermectin cream1% 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 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 permetrin 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)

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+98 31 3236 8244

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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 cutaneus 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 permetrin 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 wil move in the table from starting point horizentally to the left.then we will write assignmented treatment by intended randomized number and when the first patient will enroll,the first assignmented 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 agenand 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

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Province

Isfehan

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 permetrin 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 cutaneus lesions for 20 papulopustular rosacea patients and photography from their cutaneus 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 cutaneus lesions for 20 papulopustular rosacea patients and photography from their cutaneus 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
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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?
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
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Person responsible for updating data

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Position
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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