Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of permethrin 5% cream versus metronidazole 0.75% gel on skin region in patients with papulopustular rosacea: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of Permethrin 5% cream versus metronidazole 0.75% gel on skin region in patients with papulopustular rosacea. Design: a randomized clinical trial. Setting and conduct: The eligible patients with papulopustular rosacea who will refer to Farshchian Hospital during the study period will be enrolled into the trial. Inclusion criteria: affected with papulopustular rosacea. Exclusion criteria: mild rosacea stage 1 with mild erythema without lesions; presence of ocular signs or symptoms; steroidal rosacea; previous history of sensitivity to permethrin or metronidazole; breastfeeding. Intervention group: Treatment with topical permethrin 5% cream twice a day for 12 weeks. Control group: Treatment with topical metronidazole 0.75% gel twice a day for 12 weeks. Primary outcome: Assessing the number of papule and pustule before treatment and 6 and 12 weeks after treatment by physical examination. Secondary outcome: Scoring the erythema of skin lesions using Investigator Global Assesment (IGA) before treatment and 6 and 12 weeks after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508169014N75**
Registration date: **2015-08-25, 1394/06/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-08-25, 1394/06/03

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of permethrin 5% cream versus metronidazole 0.75% gel on skin region in patients with papulopustular rosacea: a randomized clinical trial

Public title

Effect of permethrin 5% cream versus metronidazole 0.75% gel on skin region in patients with papulopustular rosacea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: affected with papulopustular rosacea. Exclusion criteria: mild rosacea stage 1 with mild erythema without lesions; presence of ocular signs or

symptoms; steroidal rosacea; previous history of sensitivity to permethrin or metronidazole; breastfeeding.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Postal code
6517838695

Approval date
2014-01-13, 1392/10/23

Ethics committee reference number
D/P/16/35/9/3562

Health conditions studied

1

Description of health condition studied
Papulopustular rosacea

ICD-10 code
L71

ICD-10 code description
Rosacea

Primary outcomes

1

Description
Assessing the number of papule and pustule

Timepoint
before treatment and 6 and 12 weeks after treatment

Method of measurement
by physical examination

Secondary outcomes

1

Description
Scoring the erythema of skin lesions

Timepoint
before treatment and 6 and 12 weeks after treatment

Method of measurement
using Investigator Global Assesment (IGA)

Intervention groups

1

Description
Treatment with topical permethrin 5% cream twice a day for 12 weeks

Category
Treatment - Drugs

2

Description
Treatment with topical metronidazole 0.75% gel twice a day for 12 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Farshchian Hospital

Full name of responsible person
Dr Zoha Dehnavi

Street address
Farshchian Hospital, Mirzadeh Eshghi Ave.

City
Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for Research the Technology,

Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Farshchian Hospital

Full name of responsible person

Dr Zoha Dehnavi

Position

Resident of Dermatology

Other areas of specialty/work

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Farshchian Hospital

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Position

Dermatologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

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Associate Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty