

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Assessment (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)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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**

Ethics 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 Assessment (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
City
 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
Street address
 Farshchian Hospital, Mirzadeh Eshghi Ave.
City
 Hamadan
Postal code
Phone
 +98 81 3827 4184
Fax
Email
 zoha_de_f@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
 Farshchian Hospital

Full name of responsible person
 Dr Gholamreza Eshghi
Position
 Dermatologist
Other areas of specialty/work
Street address
 Farshchian Hospital, Mirzadeh Eshghi Ave.
City
 Hamadan
Postal code
Phone
 +98 81 3827 4184
Fax
Email
 gholamrezaeshghi58@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
 Department of Epidemiology
Full name of responsible person
 Dr Jalal Poorolajal
Position
 Associate Professor
Other areas of specialty/work
Street address
 School of Public Health, Hamadan University of
 Medical Sciences, Shahid Fahmideh Ave
City
 Hamadan
Postal code
 6517838695
Phone
 +98 81 3838 0090
Fax
Email
 poorolajal@umsha.ac.ir
Web page address

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