

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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**

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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**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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## Person responsible for scientific inquiries

**Contact**

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Farshchian Hospital

**Full name of responsible person**

Dr Gholamreza Eshghi

**Position**

Dermatologist

**Other areas of specialty/work**

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## 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**

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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*