

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of permethrin 5% topical gel in comparison with placebo on Demodex density in rosacea patients: a double-blind, randomized clinical trial

Protocol summary

Summary

This one-centered, placebo-controlled, double-blind, randomized clinical trial aimed to study the effects of permethrin 5% topical gel on Demodex density and clinical presentations of rosacea patients. Papulopustular rosacea patients, 18 years or older, with at least 5 mites per square centimeter on both sides of the face, were eligible for this study. In all, 20 eligible patients referring to the Dermatology Ward of Imam Khomeini Hospital in Tehran, from May 2011 to Mar 2014, provided informed consent to participate in this survey. Each patient randomly applied permethrin 5% gel on one side, and simultaneously the placebo gel on the other side of the face twice daily for 12 weeks. Demodex densities per square centimeter of the facial surface on the left and right sides were determined by standard skin surface biopsy at the baseline and the 2nd, 5th, 8th, and 12th weeks after the initiation. The clinical presentations of both sides of the face were assessed by photography and the clinical criteria of the National Rosacea Society Scorecard in the mentioned weeks as well.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030416837N1**

Registration date: **2014-04-21, 1393/02/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-21, 1393/02/01

Registrant information

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Recruitment status

Recruitment complete

Funding source

Deputy of Research, Pharmaceutical Sciences Branch, Islamic Azad University, Tehran, Iran

Expected recruitment start date

2011-05-22, 1390/03/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of permethrin 5% topical gel in comparison with placebo on Demodex density in rosacea patients: a double-blind, randomized clinical trial

Public title

Effects of permethrin on rosacea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Papulopustular rosacea patients; At

least 5 mites per square centimeter in the facial biopsy samples of both left and right sides; At least 18 years old, regardless of gender; Exclusion criteria: Rosacea patients with less than 5 mites per square centimeter in the facial biopsy samples of one or both left and right sides; Patients with different types of skin cancers; Patients with severe skin infections; Patients with severe burnings; Sensitivity to permethrin; Pregnant women; Breastfeeding women

Age

From **18 years** old to **120 years** old

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)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

The study groups were simply randomized based on flipping a coin. The "heads" were supposed as "right, permethrin 5%; left, placebo" and the "tails" were assumed as "left, permethrin 5%; right, placebo". Therefore, 40 half-faces were randomly divided into two equal groups for the permethrin 5% or placebo (20 half-faces in each group). For blinding, the permethrin 5% and placebo gels were filled in separate similar tubes labeled as "right" and "left". Labeling and grouping were performed by a third party. The researcher and patients did not know the contents of the tubes. Each patient randomly applied the permethrin 5% gel on the clean skin of one side of the face and the placebo gel on the other side, twice daily for 12 weeks.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Medical Researches,
Pharmaceutical Sciences Branch, Islamic Azad
University, Teh

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Pharmaceutical Sciences Branch, Islamic Azad
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Postal code

19419

Approval date

2011-03-13, 1389/12/22

Ethics committee reference number

15561

Health conditions studied

1

Description of health condition studied

Rosacea

ICD-10 code

L71

ICD-10 code description

Rosacea

Primary outcomes

1

Description

Density of Demodex mites per square centimeter of the facial surface on the left and right sides

Timepoint

Baseline and the 2nd, 5th, 8th, and 12th weeks after the initiation for both sides of the face

Method of measurement

Demodex densities per square centimeter of the facial surface on the left and right sides were determined by standard skin surface biopsy at the baseline and the 2nd, 5th, 8th, and 12th weeks after the initiation.

Secondary outcomes

1

Description

Clinical presentations of rosacea patients including: transient erythema, nontransient erythema, papules and pustules, telangiectasia, burning or stinging, plaque, dry appearance, edema, ocular manifestations, and phymatous changes.

Timepoint

Baseline and the 2nd, 5th, 8th, and 12th weeks after the initiation for both sides of the face

Method of measurement

The clinical presentations of both sides of the face were assessed by photography and the clinical criteria of the National Rosacea Society Scorecard at the baseline and the 2nd, 5th, 8th, and 12th weeks after the initiation.

Intervention groups

1

Description

Each patient randomly applied the permethrin 5% gel on the clean skin of one side of the face twice daily for 12 weeks.

Category

Treatment - Drugs

2**Description**

Each patient randomly applied the placebo gel on the clean skin of one side of the face twice daily for 12 weeks.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dermatology Ward, Imam Khomeini Hospital, Imam Khomeini Medical Center, Tehran, Iran

Full name of responsible person

Dr. Parvin Mansouri

Street address

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Grant name

8153

Grant code / Reference number

8153

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

Yes

Title of funding source

Deputy of Research, Pharmaceutical Sciences Branch, Islamic Azad University, Tehran, Iran

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**

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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