Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of permethrin 2.5% with tea tree oil topical gel in comparison with placebo on Demodex density and clinical features in rosacea patients: a double-blind, randomized clinical trial

Protocol summary

Study aim

Aimed to study the effects of permethrin 2/5% and Tea tree oil topical gel on Demodex density and clinical presentations in patients with rosacea.

Design

A double blind randomized clinical trial, with control group and parallel group design

Settings and conduct

35 patients were enrolled in the study. The patients referred to the Dermatology department at Bahman Hospital in Tehran from April 2016 to March 2017. Both patients and the researcher were blind to the contents of the tubes used for keeping drug/ placebo for the right and the left sides of the face.

Participants/Inclusion and 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; being at the age of at least 18 years old regardless of gender. Non-inclusion 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 burning; Sensitivity to permethrine; Pregnant women; Breastfeeding women

Intervention groups

Intervention group: Each patient randomly applied the permethrin 2.5% with Tea tree oil gel on the clean skin of one side of the face twice a day for 12 weeks. Placebo group: Each patient randomly applied the placebo gel on the clean skin of one side of the face twice a day for 12 weeks.

Main outcome variables

Density of Demodex mite; rosacea primary symptoms; rosacea secondary symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140304016837N4**
Registration date: **2019-01-14, 1397/10/24**
Registration timing: **retrospective**

Last update: **2019-01-14, 1397/10/24**
Update count: **0**

Registration date

2019-01-14, 1397/10/24

Registrant information

Name
Kosar Raoufinejad
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2017-04-06, 1396/01/17

Actual recruitment end date

2018-03-18, 1396/12/27

Trial completion date

2018-05-20, 1397/02/30

Scientific title

Effects of permethrin 2.5% with tea tree oil topical gel in comparison with placebo on Demodex density and clinical features in rosacea patients: a double-blind, randomized clinical trial

Public title

Effect of permethrin 2/5% with Tea tree oil in rosacea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with papulopustular Rosacea 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 **80 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

The study groups were simply randomized based on flipping a coin. The “heads” were supposed as “right, permethrin 2.5% and Tea tree oil; left, placebo” and the “tails” were assumed as “left, permethrin 2.5% Tea tree oil ; right, placebo"

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double blind study ,the content of tube was kept unknown to the researcher and patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

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

Street address

PO Box 19419, Yasaman St, Yakhchal Ave, Qolhak Ave, Shariati street

City

Tehran

Province

Tehran

Postal code

19419

Approval date

2017-02-13, 1395/11/25

Ethics committee reference number

IR.IAU.PS.REC.1395.42

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 centimeter squared 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

Standard skin surface biopsy

Secondary outcomes

1

Description

Transient erythema,

Timepoint

Baseline and the 2nd, 5th, 8th, and 12th weeks after the initiation of the study

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

2

Description
Nontransient erythema
Timepoint
Baseline and the 2nd, 5th, 8th, and 12th weeks after the initiation of the study
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

3

Description
papules and pustules
Timepoint
Baseline and the 2nd, 5th, 8th, and 12th weeks after the initiation of the study
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

4

Description
Telangiectasia
Timepoint
Baseline and the 2nd, 5th, 8th, and 12th weeks after the initiation of the study
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

Intervention groups

1

Description
Each patient randomly applied the permethrin 2.5% with Tea tree oil gel on the clean skin of one side of the face twice daily for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: 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, Bahman Hospital, Tehran, Iran
Full name of responsible person
Dr. Parvin Mansouri
Street address
Bahman Hospital, North Iran-Zamin Street, Gharb township
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
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Yasaman Ave, Yakhchal St, Qolhak St, Shariati St.
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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
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
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
Islamic Azad University
Full name of responsible person

Dr.Elnaz Ebneyamin

Position

pharmaciae doctor

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available