Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the efficacy and tolerability of adapalene gel 0.1% versus tretinoin gel 0.05% in patients with mild to moderate acne vulgaris: a double blinded randomized clinical trial

Protocol summary

Summary

Objectives: To compare the efficacy and tolerability of adapalene gel 0.1% versus tretinoin gel 0.05% in patients with mild to moderate acne vulgaris. Design: A double blinded randomized clinical trial. Setting and conduct: All eligible patients with mild to moderate acne vulgaris who will refer to clinic of Farshchian Hospital during the study period will be enrolled in to the trial. Inclusion criteria: Any patient with mild to moderate acne vulgaris without limitation of age and gender. Exclusion criteria: (a) Pregnancy or breast feeding; (b) using medication that have interaction with the drug under study. Intervention: Rubbing adapalene gel 0.1% on the area of facial acne lesion once a day for 12 weeks. Control: Rubbing tretinoin gel 0.05% on the area of facial acne lesion once a day for 12 weeks. Primary outcome: Evaluation of the improvement of based on the Global Acne Grading System with comparison of the photos taken from the location of the lesions at zero time and then at 4th and 12th weeks after treatment. Secondary outcome: (a) local dry skin through physical examination at 4th and 12th weeks after treatment; (b) local erythema through physical examination at 4th and 12th weeks after treatment; (c) local skin irritation through taking history of the patient at 4th and 12th weeks after treatment

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403109014N31**
Registration date: **2014-03-25, 1393/01/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-03-25, 1393/01/05

Registrant information

Name

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Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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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

1991-12-01, 1370/09/10

Expected recruitment end date

1992-08-30, 1371/06/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and tolerability of adapalene gel 0.1% versus tretinoin gel 0.05% in patients with mild to moderate acne vulgaris: a double blinded randomized clinical trial

Public title

Comparison of the efficacy and tolerability of adapalene gel 0.1% versus tretinoin gel 0.05% in patients with mild to moderate acne vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Any patient with mild to moderate acne vulgaris without limitation of age and gender. Exclusion criteria: (a) Pregnancy or breast feeding; (b) using medication that have interaction with the drug under study.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: 48 cans of the same color and size including 24 cans have adapalene gel 0.1% and 24 cans have tretinoin gel 0.05% will be numbered and then will be given to the patients at random. Blinding: The patients will receive cans with the same shape but different content. Thus, they will not aware of the intervention. Furthermore, the physician who will examine the patients will not be aware of the intervention. Thus, the design of the study will be double blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

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

City

Hamadan

Postal code

6517838695

Approval date

2013-02-14, 1391/11/26

Ethics committee reference number

D/P/16/35/9/4024

Health conditions studied

1

Description of health condition studied

Acne vulgaris

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

Evaluation of the improvement of acne lesions

Timepoint

at zero time and then at 4th and 12th weeks after treatment

Method of measurement

based on the Global Acne Grading System with comparison of the photos taken from the location of the lesions

Secondary outcomes

1

Description

local dry skin

Timepoint

at 4th and 12th weeks after treatment

Method of measurement

through physical examination

2

Description

local erythema

Timepoint

at 4th and 12th weeks after treatment

Method of measurement

through clinical examination

3

Description

local skin irritation

Timepoint

at 4th and 12th weeks after treatment

Method of measurement

through taking history of the patient

Intervention groups

1

Description
Rubbing adapalene gel 0.1% on the area of facial acne lesion once a day for 12 weeks.
Category
Treatment - Drugs

2

Description
Rubbing tretinoin gel 0.05% on the area of facial acne lesion once a day for 12 weeks
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Hospital
Full name of responsible person
Dr Bita Sharafi
Street address
Farshchian Hospital, Mirzadeh Eshghi Ave
City
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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
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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
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Person responsible for updating data

Contact

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