

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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

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

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 Bita Sharafi

Position

Resident of Dermatology

Other areas of specialty/work

Street address

Farshchian Hospital, Mirzadeh Eshghi Ave

City

Hamadan

Postal code

Phone

+98 81 1838 1086

Fax

Email

bita_sharafi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Farshchian Hospital

Full name of responsible person

Dr Akram Ansar

Position

Dermatologist

Other areas of specialty/work

Street address

Farshchian Hospital, Mirzadeh Eshghi Ave

City

Hamadan

Postal code

Phone

+98 81 1838 1086

Fax

Email

ansar@umsha.ac.ir

Web page address

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