

# 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

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#### 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*