

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the Efficacy and Safety of Simvastatin 2% Topical Gel with Placebo in Treatment of Acne Vulgaris Patients

#### Protocol summary

##### Study aim

The aim of this study is to compare the efficacy and safety of simvastatin 2% topical gel with placebo for acne vulgaris.

##### Design

Clinical trial with control group, community based and pragmatic with a parallel group, double blinded, randomized

##### Settings and conduct

Patient recruitment takes place at dermatology clinic of Amir-Almomenin hospital in Tehran. During the study, all the patients are visited by dermatologist for the clinical qualification, only after obtaining a written consent from by the researcher. The demographic details and quality of life characteristics are recorded, too. The patients are taken photo of both of the sides. Each patient randomly applies a thin layer of simvastatin 2% gel on one side, and concurrently after washing hands thoroughly, applies the placebo gel on the other side of the face. In the blinding process, an independent pharmacist helps. Both gel samples are prepared in similar, separated labeled tubes. The two tubes are kept inside a sealed box, therefore, all the 30 patients are blinded by this process.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria is patients with mild and moderate acne vulgaris in the global acne grading system. The exclusion criteria are pregnancy, lactation, dermatological malignancy, burning, infection, known hypersensitivity to simvastatin and receiving any topical or oral medication for acne vulgaris in the last one month.

##### Intervention groups

The patients with acne vulgaris undergo treatment with simvastatin gel 2% and placebo gel for eight weeks and two times a day. Each of the gels is allocated to each side of the face based on randomization method.

##### Main outcome variables

A significant reduction in the inflammation of acne

lesions; A remarkable decrease in the acne scores assessed by Global Acne Grading System; Improvement in quality of life of patients with acne

#### General information

##### Reason for update

##### Acronym

ADR

##### IRCT registration information

IRCT registration number: **IRCT20100119003106N38**

Registration date: **2018-07-28, 1397/05/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-07-28, 1397/05/06**

Update count: **0**

##### Registration date

2018-07-28, 1397/05/06

##### Registrant information

##### Name

Farshad Hashemian

##### Name of organization / entity

Pharmaceutical Sciences Branch, Islamic Azad University (IAU)

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2260 0037

##### Email address

hashemian.f@iaups.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-15, 1397/04/24

##### Expected recruitment end date

2018-09-20, 1397/06/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the Efficacy and Safety of Simvastatin 2% Topical Gel with Placebo in Treatment of Acne Vulgaris Patients

**Public title**

Effect of Simvastatin gel in treatment of acne

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with mild and moderate acne vulgaris

**Exclusion criteria:**

Pregnant women Breastfeeding women The patients with dermatological malignancy The patients with burning The patients with infection The patients which have known hypersensitivity to simvastatin The patients which have received any topical or oral medications for acne vulgaris in the last one month

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

Right side of the face and left side of the face serve as separate samples in this study. One of the sides receives simvastatin 2% gel and the other side receives placebo gel randomly.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomized allocation is based on a single sequence in this study, therefore, the method used is simple randomization. The unit of randomization is individual. At first, the two tubes containing simvastatin and placebo are determined by labeling and are received by the third-party in dual packages. The third-party uses random coin tossing to determine the side of the face that each of the gels should be used. Then he allocates a code to each of the packages, notes them all down and keeps them until the end of the study. The mentioned package, on the side of which the part it should be used is written, is sealed and handed on the patients. Allocation of the

mentioned package accomplishes by a random selection of one of the available codes written on the packages by the patient himself. The mentioned dual tubes are exactly the same in the case of weight and shape and so the desired allocation is concealed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

An independent pharmacist helps us in the blinding process. Both gel sample types are prepared in similar, separated labeled tubes. A random coin tossing is used by him for randomization of gel samples to two "right" and "left" groups. The two tubes are kept inside a sealed box, therefore, the researcher, the care provider, dermatologist, and the patients are blinded by this process. Data collectors and outcome assessors are blinded until the end of the research, too. Every box has a special code. Each patient is assigned one of those allocated codes by a random selection by himself.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Islamic Azad University, Pharmaceutical Sciences Branch

**Street address**

Islamic Azad University, Pharmaceutical Sciences Branch, Dr. Shariati Ave., Qolhak., Yakhchal St., Yasaman Ave., Tehran Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1941933111

**Approval date**

2017-01-05, 1395/10/16

**Ethics committee reference number**

IR.IAU.PS.REC.1395.41

**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

Acne scores in the Global Acne Grading System

#### Timepoint

Before intervention and 2, 5, 8 weeks after intervention

#### Method of measurement

The Global Acne Grading System Formula

## Secondary outcomes

### 1

#### Description

Quality of life score

#### Timepoint

Before intervention and 2, 5, 8 weeks after intervention

#### Method of measurement

The Cardiff Acne Disability Index questionnaire

## Intervention groups

### 1

#### Description

Intervention group: the use of gel simvastatin 2% on half of the face twice a day for 8 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Control group: the use of gel placebo on half of the face twice a day for 8 weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amir-al Momenin hospital

##### Full name of responsible person

Dr Roghaye Jebraeili

##### Street address

Department of dermatology, Amir-al Momenin hospital, In front of Sardar-e Jangal Park, end of Shir Mohammadi St., Naziabad, Tehran-Iran

##### City

Tehran

##### Province

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1811694784

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www.info@amhos.ir

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University, Pharmaceutical Sciences Branch

##### Full name of responsible person

Dr Mehdi Rajabi

##### Street address

No.99, Yakhchal street, Dr. Shariati Avenue Tehran

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##### Web page address

#### Grant name

Islamic Azad University

#### Grant code / Reference number

Pharmaceutical branch

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

Yes

#### Title of funding source

Islamic Azad University, Pharmaceutical Sciences Branch

#### Proportion provided by this source

100

#### Public or private sector

Public

#### 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. Mehdi Rajabi

##### Position

Assistant professor/ clinical pharmacist

##### Latest degree

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr. Roghaye Jebraeili

**Position**

Assistant professor/ dermatologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

assistant professor/clinical pharmacist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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**Province**

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**Phone**

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**Email**

mehdirj@aol.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All the data potentially can be shared after being  
unidentifiable.

**When the data will become available and for how long**

The start of the access period will be 6 months after the  
publication of the results.

**To whom data/document is available**

All the data will be available to all the people.

**Under which criteria data/document could be used**

All the data can be used by all the people with condition  
of mentioning the source.

**From where data/document is obtainable**

Applicants can refer to the clinical department of Islamic  
Azad University, Pharmaceutical Sciences branch, Dr.  
Rajabi or contact the researcher by sending email to  
faezeh.teimouri2920@gmail.com or calling  
09371432153.

**What processes are involved for a request to access data/document**

Applicants can apply for research information by visiting  
the department or by contacting the e-mail address and  
telephone number as well as providing information on  
academic studies and the purpose of requesting the  
information. Applicants must commit themselves to  
mention the source. If the request is sent six months  
after the publication of the research information, the  
researcher will send the data to the requesting party by  
email within a week.

**Comments**