

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 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

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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

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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

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Sponsors / Funding sources

1

Sponsor

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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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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