

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Effect of topical versus oral simvastatin as adjuvant therapy for treatment of patients with acne vulgaris: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of topical versus oral simvastatin as adjuvant therapy for treatment of acne vulgaris. Design: a randomized clinical trial. Setting and conduct: The eligible patients with acne vulgaris who will refer to Sina Hospital during the study period will be enrolled into the trial. Inclusion criteria: age of 18 to 65 years; moderate to severe acne vulgaris based on GAGS criteria for 6 months. Exclusion criteria: pregnancy; breastfeeding; liver disorder; renal disorder; using drug for acne during the last month. Intervention group 1: Oral azithromycin 250 mg daily for 8 weeks plus oral simvastatin 40 mg daily for 8 weeks plus topical placebo daily for 8 weeks. Intervention group 2: Oral azithromycin 250 mg daily for 8 weeks plus oral placebo daily for 8 weeks plus topical simvastatin daily for 8 weeks. Control group: Oral azithromycin 250 mg daily for 8 weeks plus oral placebo daily for 8 weeks plus topical placebo daily for 8 weeks. Primary outcome: Clinical sign of acne vulgaris before and 8 weeks after treatment using GAGS criteria. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612049014N135**

Registration date: **2016-12-07, 1395/09/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-12-07, 1395/09/17

Registrant information

Name

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Name of organization / entity

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University of Medical Sciences

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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

2016-12-21, 1395/10/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of topical versus oral simvastatin as adjuvant therapy for treatment of patients with acne vulgaris: a randomized clinical trial

Public title

Effect of topical versus oral simvastatin as adjuvant therapy for treatment of patients with acne vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 18 to 65 years; moderate to severe acne vulgaris based on GAGS criteria for 6

months. Exclusion criteria: pregnancy; breastfeeding; liver disorder; renal disorder; using drug for acne during the last month.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **69**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

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

City

Hamadan

Postal code

6517838695

Approval date

2016-11-18, 1395/08/28

Ethics committee reference number

IR.UMSHA.REC.1395.371

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

Clinical sign of acne vulgaris

Timepoint

before and 8 weeks after treatment

Method of measurement

using GAGS criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Oral azithromycin 250 mg daily for 8 weeks plus oral simvastatin 40 mg daily for 8 weeks plus topical placebo daily for 8 weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: Oral azithromycin 250 mg daily for 8 weeks plus oral placebo daily for 8 weeks plus topical simvastatin daily for 8 weeks.

Category

Treatment - Drugs

3

Description

Control group: Oral azithromycin 250 mg daily for 8 weeks plus oral placebo daily for 8 weeks plus topical placebo daily for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Anahita Ahmadvand

Street address

Sina 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

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Hamadan University of Medical Sciences, Shahid
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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**Name of organization / entity**

School of Pharmacy

Full name of responsible person

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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