

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The comparison of therapeutic effect on severity and number of skin lesions, between metformin semisolid formulation and placebo, in patients with mild to moderate Acne vulgaris.

Protocol summary

Summary

The goal of this study, is the evaluation of topical semisolid metformin formulation effect on severity and number of skin lesions in patients, suffering from mild to moderate Acne vulgaris. The patients with mild to moderate acne will be included in study. The samples which are diabetic or received any antibiotics in last 3 months will be excluded from study. twenty patients (regardless of sex) will be included in this study. The base of this semisolid formulation will be used as placebo. The study will be designed in a bilateral form and the the metformin semisolid formulation will be applied on one side of the face and the placebo will be applied on the other side for three months. The number and severity of skin lesions (comedones, papules and pustules) will be counted and evaluated within the defined periods of the treatment (at the end of the first, second and third month of the treatment) which is expected to be decreased.

General information

Acronym

The effect of topical semisolid formulation of metformin on acne.

IRCT registration information

IRCT registration number: **IRCT2017013132319N1**
Registration date: **2017-05-01, 1396/02/11**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-05-01, 1396/02/11

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of therapeutic effect on severity and number of skin lesions, between metformin semisolid formulation and placebo, in patients with mild to moderate Acne vulgaris.

Public title

The effect of topical semisolid formulation of metformin on severity and number of skin lesions in acne patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with mild to moderate acne, defined as a score of 1 to 30 on the global acne grading

system (GAGS) scale, who did not get any treatment before, or were not satisfied with their previous acne therapies, will be participated in the study after giving written informed consent. Exclusion criteria: Patients will be excluded if they are diabetic or have an uncontrolled systemic disease; have received topical anti acne therapy two months before or during the study or any systemic therapy, 30 days before or during the study; were known to be allergic or sensitive to any of the study medications or their components; have a skin disease that might interfere with the diagnosis or evaluation of their skin lesions; pregnant women and lactating ones.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shiraz University of Medical Sciences

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Shiraz- Imam Hossein square-Zand Avenue-The
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Approval date

2017-04-17, 1396/01/28

Ethics committee reference number

IR.SUMS.REC.1396.9

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**

Skin lesions

Timepoint

0 , 4 , 8 weeks

Method of measurement

Observation

Secondary outcomes**1****Description**

patients satisfaction

Timepoint

0,4,8 weeks

Method of measurement

determined by a 10 point scale ranging

Intervention groups**1****Description**

The case group, will receive semisolid formulation of metformin, twice a day, for two months and Azithromycin 250mg caplet will be used every other day.

Category

Treatment - Drugs

2**Description**

The control group will receive the base of semisolid formulation, the preparation will be administrated topically , two times in a day and for two months and Azithromycin 250mg caplet will be used every other day.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Faghihi Skin and Dermatology Clinic

Full name of responsible person

Dr Nasrin Saki

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Seyed Basir Hashemi

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Grant name

طرح های تحقیقاتی دانشگاه علوم پزشکی شیراز

Grant code / Reference number

95-01-36-13955

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

Yes

Title of funding source

Shiraz 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

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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