# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

29 Nov 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**
**Name**
Amir Azadi
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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
**Street address**
Shiraz- Imam Hossein square-Zand Avenue-The Central Building of Shiraz University of Medical Sciences-7th floor
**City**
Shiraz
**Postal code**
14336 - 71348
**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
**Street address**

Shiraz-Iimam Hossein Square- Shahid Faghihi Hospital-Skin and Dermatology Clinic

**City**
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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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Zand Ave. central building of Shiraz University of Medical Sciences

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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**

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Shahid Faghihi Skin and Dermatology Clinic- Shiraz-Iran

**Full name of responsible person**
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**Position**
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## Person responsible for scientific inquiries

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**Other areas of specialty/work**

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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*