

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### azithromycin gel 2% in comparison with clindamycin gel 1% in acne vulgaris

#### Protocol summary

##### Summary

Acne vulgaris is a multi-factorial disorder of the pilosebaceous unit, which is characterized by comedones, Papules, Pustules, cysts and scars. Using antimicrobial (both systemic and topical) is a common therapy for acne. Azithromycin is a semi-synthetic and newer macrolide that is effective in the treatment of acne and has fewer side effects compared with the conventional medications; however, few studies have been so far done on its topical formulations. The aim of this study is to evaluate the efficacy and possible side effects of azithromycin gel 2% in comparison with clindamycin phosphate 1%. This study is a double-blind clinical trial designed to compare the right and left sides of the face. Inclusion criteria: patients with mild and moderate acne in acne FDA grading scale system, 12 to 45 years-old patients, not receiving any effective systemic treatment of acne for one month prior to and during the study, and no history of any hypersensitivity to the study's medications. 40 patients with acne underwent treatment with azithromycin gel 2% and clindamycin gel 1% (of the same type and A & B labels) for two months and two times a day. Each of the gels was allocated to either left or right sides of the face based on the personal tendencies. Clinical improvement is evaluated based on enumeration of all lesions, acne severity index, and patients' satisfaction (10-point scale). The outcomes of the study will be measured at the fourth and eighth weeks of the treatment and then two months after the cessation of the treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014031216970N1**

Registration date: **2014-11-21, 1393/08/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-11-21, 1393/08/30

##### Registrant information

###### Name

AKRAM BASIRI

###### Name of organization / entity

ESFAHAN UNIVERSITY OF MEDICAL SCIENCES

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research of Isfahan University of Medical Sciences

##### Expected recruitment start date

2013-11-22, 1392/09/01

##### Expected recruitment end date

2014-07-21, 1393/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

azithromycin gel 2% in comparison with clindamycin gel 1% in acne vulgaris

##### Public title

Acne Treatment with topical gel azithromycin 2%

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

Inclusion criteria: patients with mild and moderate FDA acne grading system scale , aged 12 to 45 years, both sexes, written informed consent for participation in the study , not receiving topical antibiotics within two weeks and systemic medications that are effective in acne within a month prior to the study, no history of hypersensitivity to any of the studies medications.

Exclusion criteria: pregnancy or lactation, medical allergy or side effects, non- cooperation or lack of satisfactory treatment, the need for systemic medication during the study or concomitant use of drugs affecting acne

### **Age**

From **12 years** old to **45 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **40**

### **Randomization (investigator's opinion)**

N/A

### **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**

ETHICS COMMITTEE OF ISFAHAN UNIVERSITY OF MEDICAL SCIENCES

##### **Street address**

VICE CHANCELLOR FOR RESEARCH OF ESFAHAN UNIVERSITY OF MEDICAL SCIENCES- HEZAR JERIB AVENUE

##### **City**

ISFAHAN

##### **Postal code**

##### **Approval date**

2013-10-30, 1392/08/08

##### **Ethics committee reference number**

392518

## **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**

Severity of Acne

#### **Timepoint**

Beginning of the study design, 4th and 8th weeks of the treatment and 2 months after treatment

#### **Method of measurement**

Total count of lesions= TLC and acne severity index = ASI

### **2**

#### **Description**

Patient satisfaction

#### **Timepoint**

4th and 8th weeks of treatment and 2 months after treatment

#### **Method of measurement**

Scale of 10 ratings

## **Secondary outcomes**

### **1**

#### **Description**

Burning and itching

#### **Timepoint**

4th and 8th weeks of treatment and 2 months after treatment

#### **Method of measurement**

A scale of 4 ratings

### **2**

#### **Description**

Erythema

#### **Timepoint**

4th and 8th weeks of treatment and 2 months after treatment

#### **Method of measurement**

A scale of 4 ratings

### **3**

#### **Description**

Dry

#### **Timepoint**

4th and 8th weeks of treatment and two months after treatment

#### **Method of measurement**

A scale of 4 ratings

#### 4

**Description**

Desquamation and peeling

**Timepoint**

4th and 8th weeks of treatment and 2 months after treatment

**Method of measurement**

A scale of 4 ratings

#### 5

**Description**

Recurrence

**Timepoint**

2 months after treatment

**Method of measurement**

index of severity of acne=ASI Total lesion count = TLC

### Intervention groups

#### 1

**Description**

Intervention group 1 =the use of gel azithromycin 2% on half of the face 2 times a day for 2 months

**Category**

Treatment - Drugs

#### 2

**Description**

Intervention Group 2 (Control )=the use of gel clindamycin 1% on half of the face 2 times a day for 2 months

**Category**

Treatment - Drugs

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

ALZAHRA HOSPITAL

**Full name of responsible person**

Dr AKRAM BASIRI

**Street address**

DEPARTMENT OF DERMATOLOGY -ALZAHRA HOSPITAL-SOFFEH BLVD-

**City**

ISFAHAN

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

VICE CHANCELLOR FOR RESEARCH OF ISFAHAN UNIVERSITY OF MEDICAL SCIENCES

**Full name of responsible person**

Dr EBRAHIM ESFANDIARI

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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 OF ISFAHAN 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**

ISFAHAN UNIVERSITY OF MEDICAL SCIENCES- DEPARTMENT OF DERMATOLOGY

**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*