

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

0098

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

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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

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UNIVERSITY OF MEDICAL SCIENCES- HEZAR JERIB
AVENUE

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ISFAHAN

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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Position

ASSISTANT OF DERMATOLOGY

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