Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 of 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 SIENCES
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Iran (Islamic Republic of)
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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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City
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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Person responsible for updating data

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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