Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Topical Adapalene 0.1% Gel versus Topical Combination of (Tretinoin 0.025% and Erythromycin 4%) Gel in Treatment of AcneVulgaris

Protocol summary

Summary

To compare the efficacy of topical adapalene 0.1% gel versus a combined formula of topical tretinoin 0.025% and erythromycin 4% gel in the treatment of mild to moderate inflammatory acne vulgaris. Patients and Methods.Thirty six patients with inflammatory acne vulgaris (papules and pustules) will enrolled in the study. A split face method was used in which each patient was instructed to use a combined gel formula (tretinoin 0.025% and erythromycin 4%) on the right side of the face and adapalene 0.1% gel on the left side. Each patient must use the same amount of both gels at night. The duration of therapy is 6 weeks

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013040812758N2**
Registration date: **2013-05-01, 1392/02/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-05-01, 1392/02/11

Registrant information

Name

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Name of organization / entity

Baghdad medical college

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Iraq

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Recruitment status

Recruitment complete

Funding source

Iraqi Board for Medical specializations

Expected recruitment start date

2009-10-01, 1388/07/09

Expected recruitment end date

2010-10-01, 1389/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Topical Adapalene 0.1% Gel versus Topical Combination of (Tretinoin 0.025% and Erythromycin 4%) Gel in Treatment of AcneVulgaris

Public title

Treatment of acne vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients with mild to moderate acne vulgaris will enrolled in the study. All patients must without any systemic and / or topical treatment for at least 2 months before starting the study. Exclusion criteria: Patients excluded from the study were those with severe acne, nodulocystic acne, patients with systemic diseases, pregnant and lactating women.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iraqi Board for Medical specializations
Street address
Medical Collection Office, P.O. Box 61080 Postal Code 12114,
City
Baghdad
Postal code
12114
Approval date
2009-08-02, 1388/05/11
Ethics committee reference number
1966

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
Change in acne scoring.(mild,moderate,severe)Mild acne in which the count of pustules is less than 20 and the count of papules is less than 10.
Timepoint
Each patient was instructed to use the same amount of both gels (finger tip method), ½ hour in the 1st night then wash and increase the time by ½ hour in the successive nights till reach 8 hours; thereafter to keep the applications till morning. The duration of therapy was 6 weeks and follow up for another 6weeks.
Method of measurement
The clinical evaluation was done every 3 weeks by 2 dermatologists; the assessment was carried out by counting the inflammatory lesions (papules and pustules) and watching any local side effects

Secondary outcomes

1

Description
The satisfaction of the patient with the treatment.
Timepoint
The clinical evaluation was done every 3 weeks
Method of measurement
The satisfaction of the patients to the treatment is classified into:1- Full satisfaction.2- Partial satisfaction.3 - No satisfaction.

Intervention groups

1

Description
A split face method for application of treatment will used in which each patient instructed to use a combined gel formula of tretinoin 0.025% and erythromycin 4% on the right side of the face and adapalene 0.1% gel on the left side.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baghdad Teaching Hospital
Full name of responsible person
Ammar Faisal Hameed
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iraqi Board for Medical Specializations
Full name of responsible person
Prof.Khalifa Sharquie
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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
Iraqi Board for Medical Specializations
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

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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