

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the efficacy of topical 1 % clindamycin phosphate and niosomal clindamycin phosphate 1% solution in reduction of acne vulgaris lesions

Protocol summary

Summary

This controlled clinical trial will recruit 100 male and female patients (age: 12 to 30 years old) with mild to moderate acne (without clindamycin sensitivity) who visit the dermatology clinic of Afzalipour Hospital (Kerman, Iran). Table of random numbers will be used for random allocation of the patients. Intervention group will have to apply 1% niosomal clindamycin phosphate solution twice daily. Control group will have to apply 1% clindamycin phosphate solution twice daily. Acne severity with lesions count and type (Inflammatory and Non-inflammatory) and acne grading with Global Acne Grading System (GAGS) will be evaluated at baseline. response of treatment will be evaluated by measurement of acne severity and grading with GAGS at week 2, 4, 8, 12. Finally Changes will be compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080635524N1**
Registration date: **2017-10-19, 1396/07/27**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-19, 1396/07/27

Registrant information

Name

Hoda Badakhsh

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 34 3322 2250

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Recruitment status

Recruitment complete

Funding source

Vice chancellor research, Kerman University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of topical 1 % clindamycin phosphate and niosomal clindamycin phosphate 1% solution in reduction of acne vulgaris lesions

Public title

Effectiveness of niosomal clindamycin solution in treatment of acne

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Mild to moderate acne vulgaris; Both male and female; age (12-30 years); lack of treatment during the one month period before the study exclusion criteria: pregnancy; breast feeding; hypersensitivity to clindamycin; history of inflammatory bowel disease (IBD); history of neuromuscular junction blocker using; history of systemic retinoid using in the past 6 months; history of

oral estrogen using in the past 3 month; history of topical retinoid and oral antibiotic using in the past 1 month; history of antimicrobial soap and comedogenic products using in the past 2 weeks; history of astringents and abrasive products using in the past 1 week; hirsutism; androgenetic alopecia; Polycystic ovarian syndrome.

Age

From **12 years** old to **30 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Pardis of Kerman University of Medical Sciences, beginning of Haftbgh Alavi Highway, Kerman

City

Kerman

Postal code

7616913555

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

K/93/535

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

Acne severity

Timepoint

Baseline, two weeks after intervention ,four weeks after intervention, eight weeks after intervention, twelve weeks after intervention

Method of measurement

Inflammatory and non-inflammatory lesions count, mild acne: most non-inflammatory lesions or less than 15 inflammatory lesions, moderate acne: 15 to 50 inflammatory lesions

2

Description

Acne grading

Timepoint

Baseline, two weeks after intervention ,four weeks after intervention, eight weeks after intervention, twelve weeks after intervention

Method of measurement

Global Acne Grading system: The face is divided into five parts, forehead(2 factor), right and left cheek(2 factor), nose(1 factor), chin(1 factor), no lesions = 0, comedones = 1, papules = 2, pustules = 3 and nodules = 4. The score for each area (Local score) is calculated using the formula: Local score = Factor × Grade (0-4). The global score is the sum of local scores.

Secondary outcomes

1

Description

Erythema

Timepoint

Baseline, two weeks after intervention ,four weeks after intervention, eight weeks after intervention, twelve weeks after intervention

Method of measurement

Inspection

2

Description

Pruritus

Timepoint

Baseline, two weeks after intervention ,four weeks after intervention, eight weeks after intervention, twelve weeks after intervention

Method of measurement

Questionnaire

3

Description

Scaling
Timepoint
Baseline, two weeks after intervention ,four weeks after intervention, eight weeks after intervention, twelve weeks after intervention
Method of measurement
Inspection

Intervention groups

1

Description
Intervention group: Clindamycin phosphate niosomal solution1% twice daily
Category
Treatment - Drugs

2

Description
Control group: 1% Clindamycin phosphate solution twice daily
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour Hospital, Dermatology clinic
Full name of responsible person
Hoda Badakhsh
Street address
Afzalipour Hospital, next to Shahid Bahonar university, Imam Khomeini highway, Kerman
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhty
Street address
Ebsina street, Tahmasbabad intersection, Kerman
City
Kerman
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 Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Hoda Badakhsh
Position
Dermatology resident
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
Mahin Aflatoonian
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dermatopathology fellowship
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Person responsible for updating data

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Position

Assistant professor of dermatology

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Web page address

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