Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparing thr efficacy of topical 1 % clindamycin phosphate and niosomal clindamycin phosphate 1% solusion 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 severityand 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)
Phone
+98 34 3322 2250
Email address
m_khalili@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor researsh,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 thr efficacy of topical 1 % clindamycin phosphate and niosomal clindamycin phosphate 1% solusion 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 (12-30years); lack of treatment during the one month period before the study exclusion criteria: pregnancy; breast feeding; hypersensitivity to clindamycin; history of inflamatory bowel disease(IBD); history of neuromuscular junction blocker using; history of systemic retinoid using in the past 6 month; 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 inflamatory 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

Ebnsina 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

Street address

Dermatology Department, Afzalipour Hospital, next to Shahid Bahonar university, Imam Khomeini highway, Kerman

City

Kerman

Postal code

Phone

+98 34 3325 7651

Fax

Email

hbadakhsh@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mahin Aflatoonian

Position

dermatopathology fellowship

Other areas of specialty/work

Street address

Dermatology Department, Afzalipour Hospital, next to Shahid Bahonar university, Imam Khomeini highway, Kerman

City

Kerman

Postal code

Phone

+98 34 3325 7651

Fax

Email

maaflatoonian@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Maryam Khalili

Position
Assistant professor of dermatology

Other areas of specialty/work

Street address
Dermatology Department, Afzalipour Hospital, next to Shahid Bahonar university, Imam Khomeini highway, Kerman

City
Kerman

Postal code

Phone
+98 34 3325 7651

Fax

Email
m_khalili@kmu.ac.ir

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