Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Comparing efficacy of combination therapy with niosomal benzoyl peroxide 1% - clindamycin 1% versus niosomal Clindamycin1% in acne vulgaris: A randomized clinical trial

Protocol summary

Study aim

Comparing efficacy of combination therapy with niosomal benzoyl peroxide 1% - clindamycin 1% versus niosomal Clindamycin1% in acne vulgaris: A randomized clinical trial

Design

The study is a double-blind,randomized clinical trial with control group and parallel group design

Settings and conduct

This is a randomized double-blind clinical trial study. One hundered patients with mild to moderate acne vulgaris between 12 to 30 years old, attending Afzalipour hospital in Kerman enrolled the study. Patients were allocated to 2 groups (intervention and control) . Intervention group will receive combination of niosomal clindamycin (CL) 1% and benzoil peroxide (BPO) 1% and the control group will receive niosomal clindamycin 1%.

Participants/Inclusion and exclusion criteria

Inclusion criteria were patients with age between 12 to 30 years old. Exclusion criteria were pregnancy; lactation; history of allergy to clindamycin or BPO; previous history of inflammatory bowel disease ; colitis due to antibiotics; taking neuromuscular blockers and oral anti -acne drug since 6 months ago ; topical anti-acne drugs since 1 month ago;polycystic ovary syndrome; hirsutism

Intervention groups

Patients in case group were received niosomal combination of BPO 1% /CL1%(twice daily for 12 weeks) and in control group niosomal CL1%(twice daily for 12 weeks), respectively.

Main outcome variables

Number of lesions; severity of acne lesions ; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170806035524N5**
Registration date: **2018-08-15, 1397/05/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-15, 1397/05/24**
Update count: **0**

Registration date

2018-08-15, 1397/05/24

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

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing efficacy of combination therapy with niosomal benzoyl peroxide 1% - clindamycin 1% versus niosomal Clindamycin1% in acne vulgaris: A randomized clinical trial

Public title
Evaluating efficacy of combination therapy with niosomal benzoyl peroxide and clindamycin

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients with age between 12 to 30 years old. patients with mild to moderate acne vulgaris

Exclusion criteria:
pregnancy lactation history of allergy to clindamycin or BPO previous history of inflammatory bowel disease,colitis polycystic ovary syndrome, hirsutism, taking neuromuscular blockers or oral anti -acne drug since 6 months ago topical anti-acne drugs since 1 month ago

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

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
simple randomization was done using Minitab 16 software (Mini Tab Inc.)

Blinding (investigator's opinion)
Triple blinded

Blinding description
This is a triple-blind study for outcome assessor,patients and analyzor. Both drugs were kept in identical amber glass containers,so the evaluating physician and patients were unaware of the content of the containers.

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
Ebne Sina Ave.,Tahmasb Abad Blvd.

City
Kerman

Province
Kerman

Postal code
761614111

Approval date
2017-02-18, 1395/11/30

Ethics committee reference number
IR.KMU.REC.1395.116

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 lesion severity

Timepoint
At base line and 2,4, 8 and 12 weeks later

Method of measurement
Counting of acne lesions by physical examination, GAGS(Global Acne Grading System)

2

Description
Number of counting of inflammatory and non-inflammatory acne lesions

Timepoint
At base line and 2,4, 8 and 12 weeks later

Method of measurement
counting of acne lesions by physical examination

3

Description
Quality of life

Timepoint
At base line and 2,4, 8 and 12 weeks later

Method of measurement
by Cardiff Acne Disability Index (CADI) questionnair

Secondary outcomes

1

Description
Erythema
Timepoint
at base-line(before intervention) and at weeks 2, 4, 8,12
Method of measurement
by physical examinatin

2

Description
Scaling
Timepoint
at base-line(before intervention) and at weeks 2, 4, 8,12
Method of measurement
by physical examination and classification of the severity of adverse effects to mild, moderate and severe.

3

Description
pruritis
Timepoint
at base-line(before intervention) and at weeks 2, 4, 8,12
Method of measurement
by physical examination and classification of the severity of adverse effects to mild, moderate and severe.

Intervention groups

1

Description
Intervention group: niosomal combination of BPO 1% and CL 1% lotion. Route of administration: topical application, twice a day; duration of treatment: 12 weeks; manufacturing factory: Sorbitan monostearate (Span 60), polysorbate 60 (Tween 60) and cholesterol were purchased from Fluka, Switzerland. All other chemicals and soluble materials were prepared by Merck company, Germany.
Category
Treatment - Drugs

2

Description
Control group: niosomal CL1% lotion,Route of administration:topical aplication,twice daily,duration of treatment: for 12 weeks, manufacturing factory: Sorbitan monostearate (Span 60), polysorbate 60 (Tween 60) and cholesterol were purchased from Fluka, Switzerland. All other chemicals and soluble materials were prepared by Merck company, Germany
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour Hospital
Full name of responsible person
Mahin Aflatoonian
Street address
Imam high way,Kerman
City
Kerman
Province
Kerman
Postal code
7616913911
Phone
+98 34 3132 8328
Email
maaflatoonian@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhty
Street address
Ebne sina Avenue, Jehad Blvd
City
Kerman
Province
Kerman
Postal code
7619813159
Phone
+98 34 3226 3855
Email
abpardakhty@kmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Mahin Aflatoonian

Position
assistant professor of dermatology

Latest degree
Subspecialist

Other areas of specialty/work
Dermatology

Street address
Afzalipour Hospital, Imam high way

City
Kerman

Province
Kerman

Postal code
7616913911

Phone
+98 34 3132 8328

Email
maaflatoonian@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Mahin Aflatoonian

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Dermatology

Street address
Afzalipour Hospital, Imam high way

City
Kerman

Province
Kerman

Postal code
761691391

Phone
+98 34 3132 8328

Email
maaflatoonian@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Mahin Aflatoonian

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Dermatology

Street address
Afzalipour Hospital, Imam high way

City
Kerman

Province
Kerman

Postal code
7616913911

Phone
+98 34 3132 8328

Email
maaflatoonian@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available