

# 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 hundred 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 analyzer. 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) questionair

## 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

maafatoonian@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, Jihad Blvd

##### City

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##### Province

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##### 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

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**Province**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**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**

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**Postal code**

7616913911

**Phone**

+98 34 3132 8328

**Email**

maafatoonian@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