

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Clinical trial of the effect of topical phage cocktail for the treatment of acne vulgaris

#### Protocol summary

##### Study aim

Determining the effect of topical phage cocktail on improvement of skin lesions, including the number of lesions and inflammatory lesions, the total number of lesions, and the acne severity index.

##### Design

Clinical trial with control group, parallel groups, double-blind, randomized, phase 3 on 100 patients. Patients will be divided into two groups by a simple randomization method with a table of random numbers. In the control group, 1% clindamycin topical ointment with a gel base is applied for 8 weeks, and in the intervention group, 1% clindamycin topical ointment with a phage cocktail gel is applied for 8 weeks.

##### Settings and conduct

Patients referring to Buali skin clinic and Tooba clinic of Sari will be randomly divided into two groups of intervention and control. The present study is double-blind so that patients and physicians will be unaware of how the intervention and control groups assigned.

##### Participants/Inclusion and exclusion criteria

Patients aged 12 to 25 years with mild to moderate acne vulgaris based on the Global Acne Grading System (GAGS) will be included in the study.

##### Intervention groups

In the control group, 1% clindamycin topical ointment with a gel base is applied for 8 weeks, and in the intervention group, 1% clindamycin topical ointment with a phage cocktail gel is applied for 8 weeks. Every morning and evening, patients wash their face with non-medicated soap, then rinse and dry it thoroughly. Over an 8-week period, patients use the phage cocktail gel or the gel base in the case and control groups in the morning and evening. Clindamycin topical ointment 1% is applied in the evening in both groups. In both treatment groups, the second evening medication is applied approximately 10 to 15 minutes after the first medication.

##### Main outcome variables

Skin lesions, including the number of lesions and the acne severity index.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111224008507N7**

Registration date: **2025-02-10, 1403/11/22**

Registration timing: **prospective**

Last update: **2025-02-10, 1403/11/22**

Update count: **0**

##### Registration date

2025-02-10, 1403/11/22

##### Registrant information

##### Name

Mohammad Sadegh Rezai

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3334 2334

##### Email address

rezai@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-02-19, 1403/12/01

##### Expected recruitment end date

2026-02-20, 1404/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Clinical trial of the effect of topical phage cocktail for the treatment of acne vulgaris

**Public title**  
Evaluating the effect of topical phage cocktail for the treatment of acne

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age 12 to 25 years Mild to moderate acne vulgaris  
**Exclusion criteria:**  
Active cancer Immune system defect History of allergy Uncontrolled systemic disease Receiving topical anti-acne treatment 2 months before or during the study Systemic antibiotic treatment during the study Use of oral contraceptive pills (OCP) and spironolactone 30 days before or during the study History of treatment with systemic retinoids Having a skin disease that may interfere with diagnosis or evaluation

**Age**  
From **12 years** old to **25 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**  
Target sample size: **100**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
First, using the Random number generation plugin in excel software, a table of random numbers from 1 to 100 is prepared in a non-sequential and scattered manner, and the numbers are assigned to two intervention and control groups of 50 cases. The randomization process is performed by the methodology consultant and clinical researchers are not aware of the randomization process and will only be provided with random codes from 1 to 100.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
After selecting the samples, none of the participants will be aware of randomization and allocation to groups. Physicians will be given a table of pre-coded numbers and patients will be entered into the study in order of table numbers. Therefore, the present study will be double-blind. The phage cocktail and placebo are prepared in completely identical tubes and the pharmacist who prepares the phage cocktail and placebo labels A and B on the tubes.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

##### Street address

Vice chancellor for Research, Moallem square, Sari

##### City

Sari

##### Province

Mazandaran

##### Postal code

47128-55689

#### Approval date

2024-12-04, 1403/09/14

#### Ethics committee reference number

IR.MAZUMS.REC.1403.396

## 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

Reducing the number of skin lesions

#### Timepoint

First visit before treatment, second, fourth and eighth weeks

#### Method of measurement

Skin lesion count

### 2

#### Description

Reducing the number of inflammatory skin lesions

#### Timepoint

First visit before treatment, second, fourth and eighth weeks

#### Method of measurement

Skin lesion count

### 3

#### **Description**

Reducing the number of total skin lesions

#### **Timepoint**

First visit before treatment, second, fourth and eighth weeks

#### **Method of measurement**

Skin lesion count

### 4

#### **Description**

Reducing the acne severity index

#### **Timepoint**

First visit before treatment, second, fourth and eighth weeks

#### **Method of measurement**

Acne severity index = papules + (2 × pustules) + (comedones /4)

## **Secondary outcomes**

### 1

#### **Description**

Side effects such as redness, itching, burning, and inflammation

#### **Timepoint**

Second, fourth and eighth weeks

#### **Method of measurement**

Asking the patient or the patient's mother

## **Intervention groups**

### 1

#### **Description**

Intervention group: In the intervention group, 1% clindamycin topical ointment with a phage cocktail gel is applied for 8 weeks. Every morning and evening, patients wash their face with non-medicated soap, then rinse and dry it thoroughly. Over an 8-week period, patients use the phage cocktail gel in the intervention group in the morning and evening. Clindamycin topical ointment 1% is applied in the evening. The second evening medication is applied approximately 10 to 15 minutes after the first medication.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: In the control group, 1% clindamycin topical ointment with a base placebo gel is applied for 8 weeks. Every morning and evening, patients wash their face with non-medicated soap, then rinse and dry it thoroughly. Over an 8-week period, patients use the placebo gel in the control group in the morning and

evening. Clindamycin topical ointment 1% is applied in the evening. The second evening medication is applied approximately 10 to 15 minutes after the first medication.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Buali hospital of Sari

##### **Full name of responsible person**

Dr. Mohammad Sadegh Rezai

##### **Street address**

Pediatric Infectious Diseases Research Center, Bouali Hospital, Pasdaran Boulevard, Sari

##### **City**

Sari

##### **Province**

Mazandaran

##### **Postal code**

4815838477

##### **Phone**

+98 11 3334 2334

##### **Email**

drmsrezai@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Mazandaran University of Medical Sciences

##### **Full name of responsible person**

Dr. Ahmadali Enayati

##### **Street address**

Vice chancellor for Research, Moallem square, Sari

##### **City**

Sari

##### **Province**

Mazandaran

##### **Postal code**

4712855689

##### **Phone**

+98 11 3334 2334

##### **Email**

aenayati1372@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mohammadsadegh Rezai

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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Bouali Hospital, Pasdaran Boulevard, Sari

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

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**Position**

Professor

**Latest degree**

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**Other areas of specialty/work**

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**Fax****Email**

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**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Fatemeh Hosseinzadeh

**Position**

Research Expert

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

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**Email**

fatima.hzade@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Not applicable

**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

**Title and more details about the data/document**

Part of the data is accessible

**When the data will become available and for how long**

Access period from March 2027

**To whom data/document is available**

Physicians

**Under which criteria data/document could be used**

Systematic review articles

**From where data/document is obtainable**

Contact Dr. Mohammad Sadegh Rezai. E-mail:

drmsrezai@yahoo.com

**What processes are involved for a request to access data/document**

After contact, information is sent within a few days

**Comments**