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 ointment1% 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

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Iran (Islamic Republic of)

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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 intervemtion group in the morning and evening. Clindamycin topical ointment1% 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 ointment1% 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
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Pediatric Infectious Diseases Research Center, Bouali Hospital, Pasdaran Boulevard, Sari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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: drmsrezaii@yahoo.com
What processes are involved for a request to access data/document
After contact, information is sent within a few days
Comments