

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 Rezaei

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

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4815838477

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Ahmadali Enayati

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Vice chancellor for Research, Moallem square, Sari

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4712855689

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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

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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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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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