

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the specific bacteriophages to control of E.coli in patients with antibiotic-resistant urinary tract infections

Protocol summary

Study aim

Evaluation of the specific bacteriophages to control of E.coli in patients with antibiotic-resistant urinary tract infections

Design

A clinical trial with two groups of patients: parallel, therapeutic, blanced block randomization, double-blind (patient and physician). 20 patients referred to Sinai Hospital.

Settings and conduct

20 patients at Sina Hospital. blanced block randomization, double-blind (patient and physician). Patients are divided into two groups: Group 1: Rinsing the bladder with physiological saline plus phosphate buffer salt (PBS). Group 2: physiological saline plus Purified specific bacteriophage.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with recurrent urinary tract infections more than 3 positive cultures per year with E.coli, Age range 20-70 years, Consent to participate in the study. Exclusion criteria: pregnant women, Patients with allergies

Intervention groups

Control group: Rinsing the bladder with physiological saline with 20 cc of phosphate buffer salt. Intervention group: Rinsing the bladder with physiological saline with 20 cc of Purified specific bacteriophage.

Main outcome variables

Urine urgency, Frequent urination, Positive urine culture.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190624043991N14**

Registration date: **2021-06-18, 1400/03/28**

Registration timing: **prospective**

Last update: **2021-06-18, 1400/03/28**

Update count: **0**

Registration date

2021-06-18, 1400/03/28

Registrant information

Name

Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country

Iran (Islamic Republic of)

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mkaghamir@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-07, 1400/04/16

Expected recruitment end date

2022-04-09, 1401/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the specific bacteriophages to control of E.coli in patients with antibiotic-resistant urinary tract infections

Public title

Evaluation of the specific bacteriophages to control of E.coli

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with recurrent urinary tract infections more than 3 positive cultures per year with E.coli Age range 20-70 years Consent to participate in the study

Exclusion criteria:

pregnant women Patients with allergies

Age

From **20 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

The present study is a double-blind randomized clinical trial. For randomization, the blanced block randomization method is used to generate four blocks. Intervention group A and control group B have been determined. According to the randomization method, we expect the two groups to differ by a maximum of 2 people in terms of the number of people assigned. After the methodologist prepares the randomization sequence using the sealdenvelop (for create a randomisation list) online site, the generated sequence will be made available to a technician outside the research team. Quadruple blocks (A or B) are placed in envelopes. After the arrival of the first patient with the inclusion criteria, the envelopes are randomly selected and the type of patient group is informed to the research team through a trained technician. The patient is placed in Control group: Rinsing the bladder with physiological saline with 20 cc of phosphate buffer salt (PBS) or Intervention group: Rinsing the bladder with physiological saline with 20 cc of Purified specific bacteriophage based on the randomly selected envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients who have agreed to participate in the study and the therapist for the blinding process, envelopes related to the type of intervention are provided only to the technician. The physician (to avoid bias) and the patient are not informed of the type of intervention (physiological saline plus phosphate buffer salt or physiological saline plus Purified specific bacteriophage).

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committees in Medical Medical Research

Street address

Room 604, Sixth Floor, Central Staff Building, Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-06-06, 1400/03/16

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.221

Health conditions studied**1****Description of health condition studied**

Urinary tract infection

ICD-10 code

N39.0

ICD-10 code description

Urinary tract infection, site not specified

Primary outcomes**1****Description**

urinary bacteria in patients with antibiotic-resistant urinary tract infections

Timepoint

Twice a week for three consecutive months

Method of measurement

Collect patients' urine samples and check the bacteria count

2**Description**

frequent urination in patients with antibiotic-resistant urinary tract infections

Timepoint

Twice a week for three consecutive months

Method of measurement

Collect patients' urine samples and check the bacteria count

3

Description

dysuria in patients with antibiotic-resistant urinary tract infections

Timepoint

Twice a week for three consecutive months

Method of measurement

Collect patients' urine samples and check the bacteria count

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Rinsing the bladder with physiological saline with 20 cc of phosphate buffer salt (PBS), Twice a week for three consecutive months.

Category

Placebo

2

Description

Intervention group: Rinsing the bladder with physiological saline with 20 cc of Purified specific bacteriophage, Twice a week for three consecutive months.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Mohammad Kazem Aghamir

Street address

Urology Research Center, Sina Hospital, Imam Khomeini St, Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Sixth Floor, Central University, Keshavarz Boulevard, Quds Ave., Tehran.

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr Akram Mirzaei

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

demographic information anonymously

When the data will become available and for how long

one year after publication

To whom data/document is available

Researchers working in academia, physicians, surgeons and hospitals

Under which criteria data/document could be used

Any analysis can be done with the consent of the main researcher

From where data/document is obtainable

Sina Hospital, Urology Research Center, Head of Urology Research Center: Dr. Seyed Mohammad Kazem Aghamir 00982166348560

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

After reviewing the information by the administrator and epidemiologist, the patient information will be available for the applicant by the provision of a patient's privacy.

Comments

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