Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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+98 21 6634 8560

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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
Dr. Mohammad Ali Sahraian
Street address
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
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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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