Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the effect of probiotics on urinary tract infection in the elderly admitted in infection ward of Imam Hossain hospital of Shahroud a randomized clinical trial.

Protocol summary

Study aim

Determining the effect of probiotics on urinary tract infection in the elderly hospitalized in the infectious ward

Design

This double blind clinical trial is performed on 64 patients with urinary system infection that randomly divided into two equal groups In parallel. Block randomization method will be used for random allocation. The blocks size will be 4 and for this purpose; 16 blocks with 4 subjects in each block will be used. For selecting each blocks; dice drooped and the block number will be selected. This procedure continued to completed the allocation and reached to sample size.

Settings and conduct

This study will be a clinical trial study with a control group that will be performed on 64 patients referred to the infectious ward of Imam Hossein hospital of Shahroud. Patients must sign an informed consent form before entering the study. In this study, patients were blinded to clinical care, outcome assessor and analyzer.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Minimum age of 60 years, urinary tract infection confirmed by E. coli and consent to participate in the study. Exclusion criteria: any autoimmune disease, unstable clinical condition, recent antibiotic use in last week, any agent Obstruction is in the path of the urinary tract system, kidney failure, diabetes, kidney transplant and the need for surgery.

Intervention groups

Patients included in the study were divided into intervention and control groups. In the intervention group, in addition to routine treatment, probiotic yoghurt will be treated for 14 days. In the control group, in addition to routine treatment, routine yoghurt treatment will be performed for 14 days.

Main outcome variables

Reduce the clinical symptoms of urinary tract infection including: fever, dysuria, recurrence, and urgency; Reducing the number of bacteria in urine analysis; Negative urine culture;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100102002954N18**
Registration date: **2020-01-09, 1398/10/19**
Registration timing: **prospective**

Last update: **2020-01-09, 1398/10/19**
Update count: **0**

Registration date

2020-01-09, 1398/10/19

Registrant information

Name

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Name of organization / entity

Shahroud University of Medical Ssciences and Health

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of probiotics on urinary tract infection in the elderly admitted in infection ward of Imam Hossain hospital of Shahroud a randomized clinical trial.

Public title

Evaluation of the effect of probiotics on urinary tract infection in the elderly

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with at least 60 years of age, Patients with a urinary tract infection proven by E. coli, Having the consent to participate in the project.

Exclusion criteria:

Any kind of autoimmune disease, Unstable clinical condition, Taking antibiotics in the last week, Kidney failure, Any obstructive factor in the path of the urinary tract system, Diabetes, The existence of a transplanted kidney, Need for surgery.

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done using permuted block randomization method using blocked random allocation syntax in SPSS software. For calculation sample size, number of blocks and block size was determined. Block size was 4. Allocation concealment was done using closed opaque envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients; clinical caregiver,outcome evaluator and analyzer it are blinded. The division of patients into two groups A and B is done by a qualified nurse who has no knowledge of the actions performed in the two groups. Do clinical examination of patients and results recorder will be done by a qualified nurse without any knowledge of the type of intervention and patients group.

Placebo

Not used

Assignment

Parallel

Other design features

The patients enrolled in the study are divided into intervention and control groups. Patients in the intervention group will receive 250 ml of probiotic yoghurt twice daily (14 days) in addition to receiving routine treatment including appropriate serum and appropriate antibiotics. Patients in the control group will receive 250 ml of standard yoghurt twice daily (14 days) as the intervention group in addition to routine treatment including appropriate serum and antibiotics.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences; 7 Tir squer, Shahroud

City

Shahroud

Province

Semnan

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3616647555

Approval date

2018-07-22, 1397/04/31

Ethics committee reference number

IR.SHMU.REC.1397.082

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

Decrease in clinical symptoms of urinary tract infection including: fever, dysuria, recurrence and urgency.

Timepoint

Daily

Method of measurement

Patient examination and patient interview

2

Description
Reduce the number of bacteria in urine analysis
Timepoint
Two daily
Method of measurement
Standard urinalysis test

3

Description
Negative urine culture
Timepoint
Weekly
Method of measurement
Standard urine culture test

Secondary outcomes

1

Description
Recurrence of urinary tract infection
Timepoint
Monthly for three months
Method of measurement
Standard urine culture test

Intervention groups

1

Description
Intervention group: Patients in the intervention group will receive 250 ml of probiotic yoghurt twice daily for 14 days in addition to receiving routine therapy including appropriate serum and antibiotics.
Category
Treatment - Other

2

Description
Control group: Patients in the control group will receive 250 ml of standard yoghurt twice daily for 14 days in addition to receiving routine therapy including appropriate serum and antibiotics.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital of Shahroud
Full name of responsible person
Dr. Ehsan Nezakati
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice chancellor for research; Shahroud University medical and 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

Shahroud University of Medical Sciences

Full name of responsible person
Dr. Fatemeh Ghabel

Position
General Practitioner

Latest degree
Medical doctor

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

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