

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of probiotics in the prevention of urinary tract infections in elderly patients hospitalized in intensive care units

Protocol summary

Summary

The aim of the study is evaluating the effect of probiotic in urinary tract infection. The inclusion criteria is the patients who admitted to intensive care unit and aged sixty and more, without any limitation for taking oral medicine. The exclusion criteria are the patients who have a history of chemotherapy, acute bowel obstruction, short bowel syndrome and acute pancreatitis. The study is a double blind randomized clinical trial. Fifty patients will enter to the study using random number table and will be allocated between two intervention and control groups. All patients will take two capsules daily for a week. The capsule used in intervention group contains lactocare. In control group, the capsules are as the same as intervention group, but without active material (placebo). For all patients, demographic data included age and gender will be collected. The urine analysis and the urine culture will be done for all patients in the admission day, and a week after the end of intervention (completion of taking the capsules). Finally, mortality rate will be measured one month later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111530906N1**

Registration date: **2017-02-21, 1395/12/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-21, 1395/12/03

Registrant information

Name

Sara Minaeian

Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Iran University Medical of Sciences

Expected recruitment start date

2015-10-01, 1394/07/09

Expected recruitment end date

2016-10-01, 1395/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotics in the prevention of urinary tract infections in elderly patients hospitalized in intensive care units

Public title

Studying the effect of probiotics in the prevention of urinary tract infection among elderlies

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: The inclusion criteria included elder patients who aged sixty and more, and were admitted to the ICU, and did not have any limitation for taking medicine orally; Exclusion criteria: included the patients

who had a history of chemotherapy previously and right now, acute bowel obstruction, short bowel syndrome and acute pancreatitis.

Age

From 60 years old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 53

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Postal code

Approval date

2015-05-18, 1394/02/28

Ethics committee reference number

IR.IUMS.REC.1394.92112497004

Health conditions studied

1

Description of health condition studied

Prevention of Urinary Tract Infections

ICD-10 code

N39-0

ICD-10 code description

Urinary tract infection, site not specified Use additional code (B95-B98), if desired, to identify infectious agent.

Primary outcomes

1

Description

Leukocyturia

Timepoint

Before intervention and a week after completion of taking the capsules

Method of measurement

Urinary analysis

2

Description

urinary tract infection

Timepoint

Before intervention and a week after completion of taking the capsules

Method of measurement

urinary culture

Secondary outcomes

1

Description

Mortality

Timepoint

On 30th day of intervention

Method of measurement

Followed up by phone call

Intervention groups

1

Description

Intervention group: Patients in this group received probiotic capsules containing 107×5 CFU viable lyophilized bacteria including 4 strains of Lactobacillus (Lactobacillus acidophilus, Lactobacillus rhamnosus, Lactobacillus Gasser and Lactobacillus Plantarm), twice a day for seven days.

Category

Prevention

2

Description

Control group: Patients in this group took the same shape capsules without active ingredient (placebo), twice a day for seven days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Intensive care unites 's Rasool Akram Hospital

Full name of responsible person

Mahshid Talabitaheer

Street address

Rasool Akram Hospital, Mansouri street, Sattar Khan street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mahshid Talebitaheer

Street address

Rasool Akram Hospital, Mansouri street, Sattar Khan street, Tehran

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Niksolat

Position

Geriatrics Resident in Training

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty