

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Study of probiotic complementary effects in combination with Antibiotic in treatment of Recurrent urinary tract infection in Female patients: A Randomized Clinical Trial

Protocol summary

Summary

The study aims to evaluate the effects of probiotic complementary in combination with Antibiotic in treatment of Recurrent urinary tract infection. The main inclusion criteria include: age 18-80 years old; Female patients; Definitive diagnosis of Recurrent urinary tract infection confirmed by a specialist. Exclusion criteria include: presence of anatomic disorder, history of predisposing disease like diabetes mellitus. Plan: this is a randomized clinical trial, 162 patients with Recurrent urinary tract infection referring to urology clinic of Baghiatallah Hospital in Tehran will enter the study. Interventions: After the random selection of patients, Familact Capsule and Routine Antibiotic will be prescribed orally to the intervention group and the control group will receive only routine antibiotics, for 1 month. Primary outcome is presence of urinary tract infection defined by urine analysis and urine culture.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090323871N1**
Registration date: **2016-02-06, 1394/11/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-06, 1394/11/17

Registrant information

Name

Seyyed Ebrahim Moussavi Mirak

Name of organization / entity

Baghiatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8126 3692

Email address

se.moussavi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Nephrology and Urology Research Center, Baqiyatallah University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of probiotic complementary effects in combination with Antibiotic in treatment of Recurrent urinary tract infection in Female patients: A Randomized Clinical Trial

Public title

Study of probiotic complementary effects in combination with Antibiotic in treatment of Recurrent urinary tract infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: age 18-80 years old; Female patients; Definitive diagnosis of Recurrent urinary tract infection confirmed by a specialist. Exclusion Criteria: presence of anatomic disorder, history of predisposing disease like

diabetes mellitus.

Age

From **18 years** old to **80 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **162**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baghiatallah University of Medical Sciences

Street address

Baghiatallah University of Medical Sciences, Molasadra Street, Vanak Square, Tehran

City

Tehran

Postal code

Approval date

2015-07-23, 1394/05/01

Ethics committee reference number

ir.bmsu.REC.1394.108

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

Presence of Urinary tract infection

Timepoint

1, 3 and 6 month after intervention

Method of measurement

Evaluation of Lower urinary tract symptoms by history taking, physical examination, Urinalysis and Urine Culture

Secondary outcomes

1

Description

recurrence rate of Urinary tract infection

Timepoint

1, 3 and 6 month after intervention

Method of measurement

Urinalysis and Urine Culture

Intervention groups

1

Description

control group: oral prescription of Antibiotics based on Urine Culture, daily, for 1 month.

Category

Treatment - Drugs

2

Description

Intervention group: oral prescription of Antibiotics based on Urine Culture and a Familact capsule, daily, for 1 month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urology clinic of Baghiatallah Hospital in Tehran

Full name of responsible person

Seyyed Ebrahim Moussavi Mirak

Street address

Baqiyatallah Hospital, Molasadra Street, Vanak Square, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nephrology and Urology Research Center,
Baqiyatallah University of Medical Sciences

Full name of responsible person

Shahin Abbaszadeh

Street address

Nephrology and Urology Research Center,
Baqiyatallah University of Medical Sciences,
Molasadra Street, Vanak Square, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Nephrology and Urology Research Center, Baqiyatallah
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

Nephrology and Urology Research Center,
Baqiyatallah University of Medical Sciences

Full name of responsible person

Fatemeh Heidari

Position

Endourologic Laparoscopic Fellowship, Faculty
Member

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Seyyed Ebrahim Moussavi

Position

Resident of Urology

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Baghiatallah University of Medical Sciences

Full name of responsible person

Seyyed Ebrahim Moussavi Mirak

Position

Resident of Urology

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Web page address

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