

# 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**

**Street address**

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

**City**

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**Phone**

+98 21 8126 2073

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fhei50@yahoo.com

**Web page address**

## 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**

**Street address**

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

**City**

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**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Baghiatallah University of Medical Sciences

**Full name of responsible person**

Seyyed Ebrahim Moussavi Mirak

**Position**

Resident of Urology

**Other areas of specialty/work**

**Street address**

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**City**

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**Postal code**

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**Fax**

**Email**

se.moussavi@bmsu.ac.ir

**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*