# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Evaluation of the effect of probiotics on the prevention of bacterial biofilm formation on double J implanted in patients due to urological problems

## Protocol summary

**Study aim**

Investigating the effect of probiotics on the prevention of bacterial biofilm formation on double J implanted in patients due to urological problems

**Design**

Using the online site sealedenvelop.com (a site for sequencing randomized block), random blocks of patients in two groups A: double J plus placebo B: double J plus probiotic. The order of patient placement is provided to the technician. The study is Double blind (patient and researcher). 108 patients referred to Sina Hospital will be studied. The study is interventional, phase 3, parallel and therapeutic.

**Settings and conduct**

This clinical trial will be performed on 108 patients with kidney stone at Sina Hospital. urology research center, Tehran, Iran. The study will be double blind (Patient and researcher). Intervention group 1: Patients receiving double J with placebo. Intervention group 2: Patients receiving double J in addition to probiotic. Placebo capsule containing sugar, which is similar to probiotic capsule in terms of appearance and quantity, and both are prescribed one per day for 4 weeks.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Consent to participate in the study, Candidate patients for double J implantation. Exclusion criteria: Anomalies of the genitourinary system, Patients who have residual stones after urinary system stone treatment, Single kidney patients, Treatment-resistant infections, Single kidney patients.

**Intervention groups**

Intervention group A: Patients receiving double J with placebo. Intervention groupB: Patients receiving double J in addition to probiotic.

**Main outcome variables**

The bacterial biofilm formation on double j. Re-formation of stone on double J stent due to the presence of citrate probiotic and the absence of probiotic. Reduction of colonization on double J stent due to the use of probiotics

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20190624043991N19**
Registration date: **2022-10-15, 1401/07/23**
Registration timing: **prospective**

Last update: **2022-10-15, 1401/07/23**
Update count: **0**

**Registration date**

2022-10-15, 1401/07/23

**Registrant information**

**Name**

Seyed Mohammad Kazem Aghamir

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 6634 8560

**Email address**

mkaghamir@tums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-11-01, 1401/08/10

**Expected recruitment end date**

2023-11-01, 1402/08/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of probiotics on the prevention of bacterial biofilm formation on double J implanted in patients due to urological problems

**Public title**

The effect of probiotics on the prevention of bacterial biofilm formation on double J

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Consent to participate in the study Candidate patients for double J implantation

**Exclusion criteria:**

Anomalies of the genitourinary system Patients who have residual stones after urinary system stone treatment Single kidney patients Treatment-resistant infections Single kidney patients

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **108**

**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 quadruple blocks.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 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. Based on the randomly selected envelope, the patient is placed in the (A) double J plus placebo or (B) double J plus probiotic treatment group.

**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 researcher (to avoid bias) and the patient are not informed of the type of intervention (double J plus placebo or double J plus probiotic). Placebo, a capsule containing sugar, which looks similar to a probiotic capsule, is prescribed for 4 weeks.

**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**

2022-01-29, 1400/11/09

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1400.1245

## 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**

The effect of probiotics on the prevention of bacterial biofilm formation on double J

**Timepoint**

Immediately after leaving double J stent

**Method of measurement**

Pathology and Laboratory diagnosis

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Intervention group: Patients receiving double J with placebo.Placebo capsule containing sugar, which is similar to probiotic capsule in terms of appearance and quantity, and is prescribed once a day for 4 weeks.
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group: Patients receiving double J with probiotic capsules. Probiotic capsules are prescribed once a day for 4 weeks.
**Category**
Treatment - Drugs

## 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 - Hassan Abad St. - Tehran - Iran
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**Province**
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Dr. Akbar Fotouhi
**Street address**
Sixth Floor, Central University, Quds Ave., Keshavarz Boulevard, Tehran, Iran.
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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
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Medical Biology
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## Person responsible for scientific inquiries

**Contact**

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Tehran University of Medical Sciences

**Full name of responsible person**
Dr Mohammad Kazem Aghamir

**Position**
Head of Urology Research Center

**Latest degree**
Specialist

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Urology

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## Person responsible for updating data

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Tehran University of Medical Sciences

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Dr Akram Mirzaei

**Position**
Researcher

**Latest degree**
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Medical Biology

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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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