

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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 group B: 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 balanced 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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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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Head of Urology Research Center

Latest degree

Specialist

Other areas of specialty/work

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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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