Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative study of the effectiveness and safety of cranberry with tamsulosin and placebo in improving stent-related symptoms in patients undergoing Double-J ureteral stent placement: a three-group randomized controlled trial

Protocol summary

Study aim
Comparison of the effectiveness and safety of cranberry, tamsulosin, and placebo in improving stent-related symptoms in patients undergoing Double-J ureteral stent placement

Design
A controlled, parallel-group, triple-blind, randomized, phase 3 clinical trial on 96 patients. Graphpad.com was used for randomization via the online sealed envelope program.

Settings and conduct
The study will be performed in the Urology Department, Razi Educational and Medical Center in Rasht. This study is performed on 96 patients gradually and sequentially. Patients will be randomly assigned to 3 groups: cranberry, tamsulosin, and placebo. The patient, the researcher allocating the sample to treatment groups, and the analyst will be unaware of the type of patient grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 18 years, candidate for Double-J Ureteral Stent Placement; Exclusion criteria: Having bilateral stents, concurrent urinary tract infection, pregnancy, neurogenic bladder, overactive bladder syndrome, history of or current treatment for urinary incontinence, Lower urinary tract symptoms related to benign prostatic hyperplasia, chronic pelvic pain syndrome, use of anticholinergic, alpha-blockers, and analgesics drugs, major complications after urethroscopy surgery

Intervention groups
Intervention group 1: Daily receiving one 500mg cranberry capsule of Dayan Pharmed Behin Tolid company, until stent removal; Intervention group 2: Daily receiving one 0.4mg tamsulosin for Tasnim Pharmaceutical Company, placed in cranberry-like coatings until stent removal; Intervention group 3: Receiving one placebo daily consisting of empty cranberry capsules filled with chickpea flour, until stent removal

Main outcome variables
Urinary symptoms including dysuria, hematuria, urinary frequency and nocturia; pain-related symptoms; sexual symptoms and dysfunction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090427001853N20**
Registration date: **2025-05-13, 1404/02/23**
Registration timing: **prospective**

Last update: **2025-05-13, 1404/02/23**
Update count: **0**

Registration date
2025-05-13, 1404/02/23

Registrant information

Name
Siavash Falahatkar
Name of organization / entity
Urology Research Center
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-15, 1404/02/25
Expected recruitment end date
2025-11-16, 1404/08/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effectiveness and safety of cranberry with tamsulosin and placebo in improving stent-related symptoms in patients undergoing Double-J ureteral stent placement: a three-group randomized controlled trial

Public title
Comparison of the effectiveness and safety of cranberry with tamsulosin and placebo in improving symptoms associated with ureteral stents.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
age over 18 years Candidate for Double-J Ureteral Stent Placement
Exclusion criteria:
Insertion of bilateral stents Concurrent urinary tract infection Pregnancy Neurogenic bladder Overactive bladder syndrome History of or current treatment for urinary incontinence Lower urinary tract symptoms (LUTS) related to benign prostatic hyperplasia (BPH) Chronic pelvic pain syndrome Use of anticholinergic, alpha-blockers, and analgesics drugs Major complications after urethroscopy surgery (such as perforation, ...)
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization with blocks of 6 with a 1:1 ratio (in three groups A, B, and C) using the graphpad.com website and through the sealed envelope online program will be done. To assign the target group to one of the three study groups, the block randomization method with blocks of six will be used. Then, the participants will be allocated to one of the three groups in a 1:1 ratio according to the block randomization protocol (generated by graphpad.com website), in such a way that the researcher cannot predict which group of the intervention the next person will be placed in. In order to conceal the random assignment, the codes generated by the software will be placed in an envelope so that it is not clear which group the next person will be placed in. Concealed random assignment refers to the method used to perform the random sequence on study participants, in such a way that the assigned group is not known before the individual is assigned. In this study, the method of sealed opaque envelopes with a random sequence will be used. Based on the sample size of this study, a number of envelopes are prepared and each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the envelopes are glued shut and placed in a box in order. At the start of registration, based on the order in which eligible participants enter the study, one of the envelopes is opened in order and the assigned group of that participant is revealed.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Patients and researchers associated with patients are unaware of the patient's exposure. Each patient will be identified with a code that will be placed in an envelope. Researcher responsible for data collection (urology resident) places the patients in one of 3 groups based on random numbers generated in the software and after completing the checklist for them, each patient is identified with a code that is placed in an envelope (B, A or C). Then, the patients are referred to the Urology research center to receive the medicine (without knowing its type). The coating and appearance of all drugs are the same. Tamsulosin and placebo (Contains chickpea flour) are placed in empty cranberry capsules and will be packaged by one of the researchers (other than the researcher responsible for data collection and the researcher distributing the medicine) in one of the B, A, and C envelopes. The researcher distributing the medicine is unaware of the type of contents inside the medicine envelopes. The analyst will also be unaware of the type of grouping of the patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Vice chancellor of research and technology, Siyadati Street, Namjoo Street, Rasht
City
Rasht
Province
Guilan
Postal code
4144666949
Approval date
2025-04-09, 1404/01/20
Ethics committee reference number
IR.GUMS.REC.1404.026

Health conditions studied

1

Description of health condition studied
Urinary tract symptoms due to double-J stent insertion
ICD-10 code
R30
ICD-10 code description
Pain associated with micturition

2

Description of health condition studied
Urinary tract symptoms due to double-J stent insertion
ICD-10 code
R30.0
ICD-10 code description
Dysuria

3

Description of health condition studied
Urinary tract symptoms due to double-J stent insertion
ICD-10 code
R30.9
ICD-10 code description
Painful micturition, unspecified

4

Description of health condition studied
Urinary tract symptoms due to double-J stent insertion
ICD-10 code
R31
ICD-10 code description
Hematuria

5

Description of health condition studied
Urinary tract symptoms due to double-J stent insertion
ICD-10 code
R39.8
ICD-10 code description
Other symptoms and signs involving the genitourinary system

Primary outcomes

1

Description
dysuria
Timepoint
3 and 7 days after the start of the intervention and after the end of the intervention
Method of measurement
Ureteral Stent Symptom Questionnaire (USSQ)

2

Description
Hematuria
Timepoint
3 and 7 days after the start of the intervention and after the end of the intervention
Method of measurement
Ureteral Stent Symptom Questionnaire (USSQ)

3

Description
Frequency
Timepoint
3 and 7 days after the start of the intervention and after the end of the intervention
Method of measurement
Ureteral Stent Symptom Questionnaire (USSQ)

4

Description
Nocturia
Timepoint
3 and 7 days after the start of the intervention and after the end of the intervention
Method of measurement
Ureteral Stent Symptom Questionnaire (USSQ)

5

Description
Pain
Timepoint
3 and 7 days after the start of the intervention and after the end of the intervention
Method of measurement
Ureteral Stent Symptom Questionnaire (USSQ)

6

Description
Sexual dysfunction
Timepoint
3 and 7 days after the start of the intervention and after

the end of the intervention

Method of measurement

Ureteral Stent Symptom Questionnaire (USSQ)

Secondary outcomes

1

Description

Drug side effects

Timepoint

From the start of the intervention to the end of the intervention

Method of measurement

Patient report in person or by phone

Intervention groups

1

Description

Intervention group 1: daily receiving one 500 mg cranberry capsule of Dayan Pharmed Behin Tolid company, from the first day after stent placement until the stent removal

Category

Treatment - Drugs

2

Description

Intervention group 2: daily receiving one tamsulosin 0.4 mg PORTRAL OPAS for Tasnim Pharmaceutical Company, placed in cranberry-like coatings, from the first day after stent placement until the stent removal

Category

Treatment - Drugs

3

Description

Control group: Receiving one placebo daily, consisting of empty cranberry capsules filled with chickpea flour, from the first day after stent placement until stent removal

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr. Reza Shahrokhi Damavand

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Urology Department, Razi Hospital, Sardar-e-Jangal street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urology Research Center, Guilan University of Medical Sciences

Full name of responsible person

Siavash Falahatkar

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urc1384@yahoo.com

Grant name

10506

Grant code / Reference number

32

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

Yes

Title of funding source

Urology Research Center, Guilan University of Medical Sciences

Proportion provided by this source

90

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

2

Sponsor

Name of organization / entity

Vice chancellor of research and technology

Full name of responsible person
Ramyar Farzan
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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
Vice chancellor of research and technology

Proportion provided by this source
10

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
Rasht University of Medical Sciences
Full name of responsible person
Fariman Asheghpour
Position
Urology resident
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available