Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of cranberry medicine on the prevention of dysuria caused by Urodynamic study A Randomized Clinical Trials

Protocol summary

Study aim
Studying the effect of cranberry medicine on preventing dysuria caused by bladder aerodynamics

Design
Clinical trial. With control group with factorial group. Double-blind randomized with block method. Phase 3 on 74 patients.

Settings and conduct
This study is designed as a double-blind clinical trial. Women who have been referred to the relevant specialist for a bladder tap are randomly assigned to the study until the required sample size is reached according to the inclusion criteria. They are randomly assigned to a number of cranberry drugs and a number of placebos in a block. The dose of cranberry capsules is 500 mg, which the patient takes one capsule every 12 hours for a week before the bladder tap. After the aerodynamic study, within 24 to 72 hours, the first contact is within 24 hours and the second contact is 72 hours later, questions related to the occurrence of burning urination, frequent urination, urgency during defecation, and pain or discomfort in the bladder area are asked from the patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Individuals for whom a bladder tap has been requested. Age over 18 years. No previously diagnosed anatomical abnormalities of the urinary tract. No symptoms of vaginitis or cystitis. No asymptomatic bacteriuria. Exclusion criteria: Patient unwillingness to take medication.

Intervention groups
This study is designed as a double-blind clinical trial. Women who have been referred to a specialist for a bladder biopsy will be included in the study. They will be randomly assigned to a number of cranberry drugs and a number of placebos in a block design.

Main outcome variables
Insufficient voiding Dysuria Frequent urination Urgency during defecation Pain or discomfort in the bladder History of prolapse Incontinence surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250503065570N1**
Registration date: **2025-07-22, 1404/04/31**
Registration timing: **prospective**

Last update: **2025-07-22, 1404/04/31**
Update count: **0**

Registration date
2025-07-22, 1404/04/31

Registrant information

Name
Fatemeh Farahani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-26, 1404/05/04

Expected recruitment end date
2026-07-26, 1405/05/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the effect of cranberry medicine on the prevention of dysuria caused by Urodynamic study A Randomized Clinical Trials

Public title
Investigating the effect of cranberry medicine on the prevention of dysuria caused by Urodynamic study A Randomized Clinical Trials

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People for whom a bladder tape has been requested Age over 18 years old Absence of previously diagnosed anatomical abnormalities of the urinary tract No symptoms of vaginitis or cystitis Absence of asymptomatic bacteriuria

Exclusion criteria:
Patient's unwillingness to take medication

Age
From **18 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the random permutation block method will be used for randomization. For this purpose, a block of 6 will be used. In each block, the letter I (Intervention) is written on three cards and the letter P (Placebo) is written on three cards. To hide the cards, they are placed in an envelope and turned over several times so that their order is not clear. As each participant enters, a card is selected for him and the selected card is set aside. This is done for the next five patients until 6 people are identified. Then, randomization will be done in the same way for the other groups of 6 people to achieve the desired sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a double-blind study in which neither the researcher nor the patient knows which treatment is assigned to the patient. The statistical consultant performs block randomization and assigns a code to each drug, contacts the pharmacy and announces the type of drug and the code, and then the pharmacy writes the code on the drug and gives it to the patient for whom the specialist doctor has prescribed cranberry. This study has a placebo and after obtaining informed consent from the patient, some patients are given a placebo and some are given the cranberry drug itself.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Arak University of Medical Sciences

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Alam Al-Hoda Street . Shahid Shiroodi Street

City
Arak

Province
Markazi

Postal code
3819693345

Approval date
2025-04-20, 1404/01/31

Ethics committee reference number
IR.ARAKMU.REC.1404.021

Health conditions studied

1

Description of health condition studied
Dysuria caused by bladder aerodynamics

ICD-10 code
R30.0

ICD-10 code description
Dysuria

Primary outcomes

1

Description
Dysuria after bladder taping

Timepoint
Within 24 to 72 hours, first call within 24 hours and second call 72 hours later.

Method of measurement
Checklist and questions

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Each capsule of Cranfix contains approximately 500 mg of cranberry extract. Since participants are instructed to take 2 capsules per day (one every 12 hours), the total daily dose will be 2 capsules × 500 mg, 1000 mg of cranberry extract per day. Over a 1-week period, they will take a total of 7000 mg of cranberry extract. In order to emphasize the continued use of the capsules, daily telephone calls will be made to the patients in some cases. Cranfix Cranberry Fruit Extract (Vaccinium Macrocarpon L) capsules, 500 mg dose, are manufactured in Gol Daru Company, Isfahan, Soffe Industrial Estate, Iran.

Category
Treatment - Drugs

2

Description
Control group: The placebo control group will be given the same 500 mg cranberry capsule as the original drug and at the same time. Each placebo capsule of Cranfix is approximately 500 mg. Since participants are instructed to take 2 capsules per day (one every 12 hours), the total daily dose of 2 capsules × 500 mg will be 1000 mg per day. Over a 1-week period, they will take a total of 7000 mg. In order to emphasize the continuous use of the placebo capsule, daily telephone calls will be made to the patients in some cases. The placebo capsule of Cranfix Cranberry Fruit Extract (Vaccinium Macrocarpon L), 500 mg, is manufactured in Gol Daru Company, Isfahan, Soffe Industrial Estate, Iran.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghavamzadeh Clinic

Full name of responsible person
Fatemeh Farahani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Maryam Shokrpour

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information available.

Study Protocol
No - There is not 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
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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
No - There is not a plan to make this available