

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of cranberry gavage on prevention catheter related urinary tract infection in hospitalized patients at intensive care unit

Protocol summary

Study aim

Determining the effect of gavage of cranberry on the prevention of catheter-dependent urinary tract infections in patients admitted to the intensive care unit

Design

A randomized clinical trial with a control group, with two parallel groups

Settings and conduct

This study is a randomized clinical trial will be done on two groups of 100 patients who have a foley catheter that admitted to the intensive care units of Besat hospital in Hamedan . Before the intervention, patients will be randomly divided into two groups:intervention and control. Before the intervention, urine culture and complete blood cell counting(CBC) will be checked . In the intervention group, in addition to routine care from the foley catheter, a Cranberry tablet (500 mg) will be used twice a day for four days. On the fifth day, tests of urine culture and blood count of patients will be measured again. In the control group only routine care will be taken from the catheter.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients should have urinary catheters,do not having urinary tract infection before the study, do not rupture urinary tract and bladder damage.

Exclusion criteria: Exit the urethral catheter for any reason before the end of the study period, cranberry sensitivity

Intervention groups

Intervention: In the intervention group, in addition to routine care from the Foley catheter , the cranberry tablet(500mg) will be given twice a day at 9 o'clock and 5 o'clock by gavage. Control group: Control group will receive only routine care from the catheter foley .

Main outcome variables

Urinary infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160110025929N24**

Registration date: **2019-07-10, 1398/04/19**

Registration timing: **prospective**

Last update: **2019-07-10, 1398/04/19**

Update count: **0**

Registration date

2019-07-10, 1398/04/19

Registrant information

Name

Mehdi Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3422 5056

Email address

m.molavi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cranberry gavage on prevention catheter related urinary tract infection in hospitalized patients at intensive care unit

Public title

The effect of cranberry gavage on prevention catheter related urinary tract infection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients should have urinary catheters Do not have urinary tract infection before the study Do not have rupture urinary tract and bladder damage Age over 18 years

Exclusion criteria:

Exit the urethral catheter for any reason before the end of the study period Having sensitivity to cranberry

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed using 2-point permutational block method and randomization was done by computer software.

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 Hamadan university of medical sciences

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Approval date

2019-04-27, 1398/02/07

Ethics committee reference number

IR.UMSHA.REC.1398.148

Health conditions studied

1

Description of health condition studied

Urinary tracr infection

ICD-10 code

N39.0

ICD-10 code description

Urinary tract infection, site not specified

Primary outcomes

1

Description

Urinary infection

Timepoint

Before and 5 days after the intervention

Method of measurement

urine culture tests and complete blood count(CBC)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, in addition to routine care from the Foley catheter , the cranberry tablet(500mg) will be given twice a day by gavage.

Category

Prevention

2

Description

Control group: Control group will receive only routine care from the catheter foley(Washing the perineal area).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Aziz azizi

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Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saei Bashirian

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Grant name

Grant code / Reference number

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

No

Title of funding source

Deputy of research and technology

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

Hamedan University of Medical Sciences

Full name of responsible person

Azim Azizi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Vahideh Maarefian

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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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