

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of two types of indwelling catheter in prevention catheter-associated urinary tract infections in ICU patients

Protocol summary

Study aim

Comparison of two types of persistent catheter (Foley catheter with LoPro urinary catheter) in the prevention of catheter-related urinary tract infections in patients in the intensive care unit

Design

Clinical trials with control and intervention group, with parallel groups, blind, randomized

Settings and conduct

The study is carried out at the of Besat Hospital in Hamedan, and patients entering the study are enrolled in the study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria; 1-Decreased consciousness (GCS less than 9) 2-Normal body temperature (axillary =35.5-37%) 3-The doctor's order for urinary catheterization 4-Not having a urinary tract infection or bacteriuria prior to admission 5-Not having underlying diseases such as diabetes, CKD, nephrosclerosis, acute or chronic glomerulonephritis, and pyelonephritis 6-Not having immune deficiency disorders such as lupus erythematosus, rheumatoid arthritis, MS 7-Not having trauma and rupture of the urethra and bladder 8-Not getting aminoglycoside medications 9-Age over 18 years
Exclusion Criteria: 1-Exit the catheter for any reason (exits by patient or on doctor's instructions) before 3 days 2-Death or transmission of the patient before the completion of the study

Intervention groups

Patients admitted to the intensive care unit who have a Foley catheter

Main outcome variables

ESR-Leukocytosis-Type of germ - The number of germs

General information

Reason for update

Acronym

پیشگیری

IRCT registration information

IRCT registration number: **IRCT20100816004578N7**

Registration date: **2019-03-14, 1397/12/23**

Registration timing: **prospective**

Last update: **2019-03-14, 1397/12/23**

Update count: **0**

Registration date

2019-03-14, 1397/12/23

Registrant information

Name

Farshid Rahimibashar

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 811264002151

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f.rahimi@umsh.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two types of indwelling catheter in prevention catheter-associated urinary tract infections in ICU patients

Public title

Impact of two types of indwelling catheter in prevention catheter-associated urinary tract infectionson

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Decreased consciousness (less than 9 in GCS) Normal body temperature (as axillary 35.5-37%) The doctor's order for urinary catheterization Not having a urinary tract infection or bacteriuria prior to admission Not having underlying diseases such as diabetes, CKD, nephrosclerosis, acute or chronic glomerulonephritis, and pyelonephritis Not having immune deficiency disorders such as lupus erythematosus, rheumatoid arthritis, MS Not having trauma and rupture of the urethra and bladder Not getting aminoglycoside medications Age over 18 years

Exclusion criteria:

Exit the catheter for any reason (exits by patient or on doctor's instructions) before 3 days Death or transmission of the patient before the completion of the study

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

All patients with entry criteria will be identified. Then, the allocation of patients to the Foley catheter group or the LoPro urinary catheter will be randomized. The computer generated randomization list is first generated and the randomly assigned duplicate blocks (1: 1) are printed on paper and packed in envelopes. Each envelope will be opened after receiving written consent from the patient's ward.

Blinding (investigator's opinion)

Double blinded

Blinding description

Since patients with a decreased level of consciousness, blind blindness is not conceptualized. The laboratory warden will not be aware of the groups being studied. Also, since the difference is only in the physical structure of the bladder end of the catheter and the visible parts in the two types of catheter are similar, therefore, nurses working in the ICU will not be aware of the type of catheter used for the patient.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamedan University of Medical Sciences

Street address

Hamadan University of Medical Science, Shahid Fahmide boulevard, Hamadan

City

Hamedan

Province

Hamadan

Postal code

6514845411

Approval date

2019-01-28, 1397/11/08

Ethics committee reference number

IR.UMSHA.REC.1397.766

Health conditions studied**1****Description of health condition studied**

Urinary tract infection

ICD-10 code

N30.2

ICD-10 code description

Other chronic cystitis

Primary outcomes**1****Description**

Number Bacteria

Timepoint

Before and After 1,2,3 days

Method of measurement

Urine Culture

2**Description**

Type of Bacteria

Timepoint

Before and After 1,2,3 days

Method of measurement

Urine Culture

Secondary outcomes

1

Description

ESR

Timepoint

Before and After 3 days

Method of measurement

Vstrgryn

2

Description

Leukocytosis

Timepoint

Before and After 3 days

Method of measurement

Cell Blood Count

3

Description

Nitrite

Timepoint

Before and After 1.2.3 days

Method of measurement

Urinalysis

4

Description

Body temperature

Timepoint

Before and After 1.2.3 days

Method of measurement

Axillary with medical thermometer

5

Description

pH of the urine

Timepoint

Before and After 1.2.3 days

Method of measurement

DIP STICK

6

Description

The color of the urine

Timepoint

Before and After 1.2.3 days

Method of measurement

DIP STICK

Intervention groups

1

Description

Intervention group: In this group of a type of catheter with oval holes on both sides, the LoPro (Low Profile) catheter is a short and an end tip slightly higher than the balloon loop

Category

Prevention

2

Description

Control group: Use Foley Root Catheter in section

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Farshid Rahimi Bashar

Street address

General ICU, BESAT Hospital, Motahhari boulevard, Resalat Square

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6514845411

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f.rahimi@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences

Full name of responsible person

Saeid Bashirian

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Hamadan University of Medical Science, Shahid Fahmide boulevard, Hamadan

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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 for Research and Technology of
Hamadan 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

Hamedan University of Medical Sciences

Full name of responsible person

Farshid Rahimi Bashar

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Farshid Rahimi Bashar

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Farahnaz Ramezani

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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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

Undecided - It is not yet known if there will be 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

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

Data Dictionary

Not applicable

Title and more details about the data/document

All the studied demographic and clinical characteristics
will be issued.

When the data will become available and for how long

The study protocol will be issued in the article.

To whom data/document is available

After publishing the results, the data will be provided to
the requesting users.

Under which criteria data/document could be used

The data will be available for use in the systematic review and meta-analysis studies.

From where data/document is obtainable

Dr. Mahnaz Kitabani and Mrs. Farahnaz Ramezani (Project executives)

What processes are involved for a request to access data/document

By sending an email request to the project executives.

Comments