

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Sep 2026

The comparison of multi-modality catheterization on bacteriuria and catheter - associated urinary tract infections

Protocol summary

Summary

In hospitals one of the key actions is the reduction of infections related to the care measures, that in developed countries it gains special attention for patients health. Since catheter- associated urinary infection creates in 80% case as a consequence of urinary catheterisation, the prevention of these infections has an important role to reduce infections related to the treatment cares. Therefore, the present study aims to comparison of multi-modality catheterization on bacteriuria and catheter - associated urinary tract infections This study is a randomized and controlled double blind clinical trial. 200 patients aged between 18-75 that they need the (insertion) of urinary catheter (folly) put in four groups including catheterilization in usual method (control) and catheterization with daily change of sterile urinary bag, and catheterization with designed sheath catheter and catheterization with candom catheter. In each two groups, immediately after the insertion and during the time of removing the urethral catheter, the urine sample was collected in sterile method and was sent to laboratory in order to test bacteriuria. The demographic information will made and collect by using the researcher made questionnaire and analysis by Spss 20 software and descriptive statistic tests (frequency) relative frequency, mean, and standard deviation (SD). The comparison of multi-modality catheterization on bacteriuria and catheter - associated urinary tract infections

General information

Acronym

Catheter - Associated Urinary Tract Infections(CA-UTIs)

IRCT registration information

IRCT registration number: **IRCT201607263912N8**

Registration date: **2016-08-07, 1395/05/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-07, 1395/05/17

Registrant information

Name

Kobra Nourian

Name of organization / entity

Sharekord University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 38 1333 5648

Email address

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Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of multi-modality catheterization on bacteriuria and catheter - associated urinary tract infections

Public title

The comparison of multi-modality catheterization on bacteriuria and catheter - associated urinary tract infections

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all the patients that hospitalized with several reasons and needed the preparation for urethra (Foley) catheter; age between 18 to 75 years old. Exclusion criteria: the positive urinary culture at first of the study; the surgery on urinary system and anti-biotic consumption.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences, Kashani Blvd.

City

Shahrekord

Postal code

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

739

Health conditions studied

1

Description of health condition studied

UTI

ICD-10 code

N39.0

ICD-10 code description

Urinary tract infection, site not specified

Primary outcomes

1

Description

Bacteriuria

Timepoint

immediately before insertion the urethral catheter and, immediately before removing the urethral catheter,

Method of measurement

cfu/ml

Secondary outcomes

empty

Intervention groups

1

Description

In evacuated urinary bag group (usual method), The silicon urethral catheter was established with routine method and the usual way by using aseptic method, and the urinary bag was evacuated after each completion. immediately before insert urethral catheter and before removing the urethral catheter, the urinary sample with aseptic method from urinary catheter by using 10cc sterile syringe prepare and sent to the laboratory to investigate for bacteriuria in less than 30 minutes.

Category

Prevention

2

Description

In change urinary bag group, The silicon urethral catheter establish with aseptic method. Then, in each urinary bag completion, this bag was evacuated and changed daily. immediately before insert urethral catheter and before removing the urethral catheter, the urinary sample with aseptic method from urinary catheter by using 10cc sterile syringe prepare and sent to the laboratory to investigate for bacteriuria in less than 30 minutes.

Category

Prevention

3

Description

In condom catheter group, The condom catheter establish with aseptic method. Immediately before insert urethral catheter and before removing the urethral catheter, the urinary sample with aseptic method from urinary catheter by using 10cc sterile syringe prepare and sent to the laboratory to investigate for bacteriuria in less than 30 minutes

Category

Prevention

4

Description

In designed catheter sheath group, The designed catheter sheath establish with aseptic method. Immediately before insert urethral catheter and before removing the urethral catheter, the urinary sample with aseptic method from urinary catheter by using 10cc sterile syringe prepare and sent to the laboratory to investigate for bacteriuria in less than 30 minutes.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Kobra Noorian

Street address

Kashani Hospital, Parastar Street

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Shahrekord University of Medical Sciences.

Full name of responsible person

Mahmmod Mobasheri

Street address

Shahrekord University of Medical Sciences, Kashani Blvd.

City

Shahrekord

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, Shahrekord University of Medical Sciences.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Kobra Noorian

Position

Faculty member

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty