Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Effect of Betadine and Chlorhexidine for periurethral cleaning before Catheterization on Bacteriuria and pyuria in female patients hospitalized in emergency of Alzahra hospital of Isfahan University of Medical Sciences 2018

Protocol summary

Study aim

Comparison of Effect of Betadine and Chlorhexidine for periurethral cleaning before Catheterization on Bacteriuria and pyuria in female patients hospitalized in emergency .

Design

This study was a single-blind clinical trial. Samples from hospitalized women in the emergency department were selected by random sampling and divided into two groups of 36, chlorhexidine and betadine.The perineal area and the urinary tract were washed with the Antiseptic. A urin sample was taken immediately after catheterization and 72 hours and 5 days after catheterization.The bacteriuria, pyuria and microorganism count were obtained from the test results.

Settings and conduct

Samples from hospitalized women in emergency department of university hospital were selected by random sampling and divided into two groups .The perineal area and the urinary tract were washed with the Antiseptic. A urin sample was taken immediately after catheterization and72 hours and 5 days after catheterization.The bacteriuria, pyuria and microorganism count were obtained from the test results.

Participants/Inclusion and exclusion criteria

In this study, female patients 18 years of age who need Foley catheter for 5 days can be evaluated with their satisfaction. Patients who are admitted with the Foley catheter and diagnosed with urinary tract infections and on the other hand A history of hypersensitivity to the two solutions used in the intervention report are not included in the study.

Intervention groups

In this study, the effect of betadine and chlorhexidine in washing the perineal area and the urethra before the catheter is admitted female patients, in order to determine the effect of each of them in reducing the bacterial and pyuria of the Foley catheter.

Main outcome variables

Bacteriuria and pyuria in urine specimens

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170712035044N2**
Registration date: **2019-07-20, 1398/04/29**
Registration timing: **retrospective**

Last update: **2019-07-20, 1398/04/29**
Update count: **0**

Registration date

2019-07-20, 1398/04/29

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7544

Email address

somayehghafari@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-05, 1397/11/16

Expected recruitment end date
2019-06-20, 1398/03/30
Actual recruitment start date
2019-02-09, 1397/11/20
Actual recruitment end date
2019-06-22, 1398/04/01
Trial completion date
2019-06-22, 1398/04/01

Scientific title
Comparison of Effect of Betadine and Chlorhexidine for periurethral cleaning before Catheterization on Bacteriuria and pyuria in female patients hospitalized in emergency of Alzahra hospital of Isfahan University of Medical Sciences 2018

Public title
Antiseptic effect on bacteriuria of patients with catheterization
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients need a Foley catheter for at least 5 days. There is no obvious tissue damage to the mucosa and skin of the genital area in the patient. There are no symptoms of urinary tract infection including fever above 38 °, pain in the suprapubic area, frequent urination, burning in the urine. Absence of foley catheter at admission No history of hypersensitivity to betadine and Chlorhexidine substances.
Exclusion criteria:
Unwillingness of the patient and family to continue participating in the study. Need to leave the patient's catheter sooner than 5 days
Age
From **18 years** old to **90 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **72**
Actual sample size reached: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the sampels divided into two intervention groups A and B by using random numbers and Randomizer software. group A with iodine and group B with Chlorhexidine was done periurethral cleaning before Catheterization .
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the researcher specifies the type of solution in each group and at the time of sampling the participant is asked about the susceptibility to both solutions, but at the time of the intervention the participant is not aware of the type of solution used.(One-way blind to the patient)
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Ethics Committee for Biomedical Research
Street address
Tehran-Ghods Town (West) - Between South Falamak and Zarafshan, Iran's Sims Avenue-Headquarters of the Ministry of Health and Medical Education, block A, thirteenth floor
City
Esfahan
Province
Isfehan
Postal code
۸۱۴۵۵۶۱۸
Approval date
2019-01-23, 1397/11/03
Ethics committee reference number
1397.378.IR.MUI.RESEARCH.REC

Health conditions studied

1

Description of health condition studied
Bacteriuria
ICD-10 code
N39.0
ICD-10 code description
Urinary tract infection, site not specified

Primary outcomes

1

Description
Bacteriuria in patients with Foley catheter
Timepoint
Immediately after catheterization, bacteriuria were evaluated 72 hours and 5 days after catheterization.
Method of measurement
By sending a urine test and culture the urine in the Blood Agar environment.

2

Description

pyuria in patients with Foley catheter

Timepoint

Immediately after catheterization, pyuria were evaluated 72 hours and 5 days after catheterization.

Method of measurement

By sending a urine test and culture in the Blood Agar environment.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, 36 female patients needed Foley Catheter and conditions for entry into the study, the urethra and perinea area were washed with iodine, and the urine specimen in the 3 periods immediately after the catheter was 72 hours Next and 5 days later.

Category

Prevention

2

Description

Intervention group2: Intervention group 1: In this group, 36 female patients needed Foley Catheter and conditions for entry into the study, the urethra and perinea area were washed with Chlorhexidine, and the urine specimen in the 3 periods immediately after the catheter was 72 hours Next and 5 days later.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital affiliated to Isfahan University of Medical Sciences

Full name of responsible person

Somayeh Ghafari

Street address

Hezar Jarib St., Isfahan University of Medical Sciences, Nursing and Midwifery Faculty

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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Bldg No. 4, Isfahan University of Medical Sciences and Health Services.Vice-Chancellery for Research and Technology

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Somaye Ghafari

Position

Assistant Professor of Nursing Midwifery

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact
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Esfahan University of Medical Sciences
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Person responsible for updating data

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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
Confidentiality of patient information
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