Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Impact of bladder irrigation with normal saline solution on the control of cystitis in the patients having urinary catheters in the Intensive Care Unit

Protocol summary

Summary

The present Single blind clinical trial will be conducted to determine the effects of bladder irrigation with normal saline on cystitis of catheterized patients in an Intensive Care Unit. 60 eligible patients will be randomly allocated to the experiment group (n=30) or control group (n=30). The inclusion criteria are: having urinary catheter, over 18 years old, suspected or asymptomatic bacteriuria induced by a urinary catheter. The exclusion criteria are: urinary catheter removal, patient's transfer or death, having chronic disease(Immunodeficiency, Diabetes mellitus, recurrent urinary tract infection before admission, anatomic problems and trauma to the to the genitourinary system, Chronic kidney disease, Acute or chronic glomerulonephritis, Pyelonephritis, the use of Aminoglycosides، laboratory observer willnot know about patients' groups. Both groups will receive the routine care and medications. But, the experiment patients will receive bladder irrigation with normal saline once a day for 3 days with 500 ml. in three doses of 150 ml.The primary outcomes:ESR, leukocytosis, nitrite, number and type of bacteria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702134578N6**
Registration date: **2017-05-04, 1396/02/14**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-05-04, 1396/02/14

Registrant information

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of bladder irrigation with normal saline solution on the control of cystitis in the patients having urinary catheters in the Intensive Care Unit

Public title

Impact of bladder irrigation on the control of cystitis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: having urinary catheter, over 18 years old, suspected or asymptomatic bacteriuria induced by a urinary catheter exclusion criteria: urinary catheter removal due to physician order or spontaneous, patient's transfer or death, having chronic diseases

(Immunodeficiency, Diabetes mellitus, recurrent urinary tract infection before admission, anatomic problems and trauma to the to the genitourinary system, Chronic kidney disease, Acute or chronic glomerulonephritis, Pyelonephritis, the use of Aminoglycosides.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomized Block

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

Postal code

Approval date
2017-01-28, 1395/11/09

Ethics committee reference number
IR.UMSHA.REC.1395.495

Health conditions studied

1

Description of health condition studied
cystitis

ICD-10 code
N30.2

ICD-10 code description
urinary tract infection,site not specified

Primary 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 3 days

Method of measurement
Urinalysis

4

Description
Number Bacteria

Timepoint
Before and After 3 days

Method of measurement
Urine Culture

5

Description
Type of Bacteria

Timepoint
Before and After 3 days

Method of measurement
Urine Culture

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the experiment patients will receive bladder irrigation with normal saline once a day for 3 days with 500 ml. in three doses of 150 ml

Category
Prevention

2

Description
Control group: The control group will receivel care routine
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Farahnaz Ramezani
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General ICU, BESAT Hospital, Motahhari boulevar, Resalat Square
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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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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
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

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Person responsible for updating data

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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