# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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**

**Name**


Farshid Rahimibashar

**Name of organization / entity**

Hamedan University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 811264002151

**Email address**

f.rahimi@umsh.ac.ir


**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
**Street address**
General ICU, BESAT Hospital, Motahhari boulevar, Resalat Square
**City**
Hamedan

## 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
**Street address**
Hamadan University of Medical Science, Shahid Fahmide boulevard, Hamadan
**City**
Hamedan
**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

**Contact**
**Name of organization / entity**
Hamedan University of Medical Sciences
**Full name of responsible person**
Farshid Rahimi Bashar
**Position**
Assistant Professor
**Other areas of specialty/work**
**Street address**
General ICU, BESAT Hospital, Motahhari boulevard, Resalat Square, Hamedan
**City**
Hamedan
**Postal code**
**Phone**
+98 81 3264 0025
**Fax**
**Email**
f.rahimi@umsh.ac.ir
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Hamedan University of Medical Sciences
**Full name of responsible person**
Farshid Rahimi Bashar
**Position**
Assistant Professor
**Other areas of specialty/work**
**Street address**
General ICU, BESAT Hospital, Motahhari boulevard, Resalat Square
**City**
Hamedan
**Postal code**
**Phone**
+98 912 581 6621
**Fax**
**Email**
f.rahimi@umsh.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Hamedan University Of Medical Sciences
**Full name of responsible person**
Farahnaz Ramezani
**Position**
Masters student
**Other areas of specialty/work**
**Street address**
General ICU, BESAT Hospital, Motahhari boulevard, Resalat Square
**City**
Hamedan
**Postal code**
**Phone**
+98 81 3826 5702
**Fax**

**Email**
ramezanifarah@gmial.com
**Web page address**

## 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*