

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of bladder irrigation with 0.2% chlorhexidine before TURP in patients with foley catheter regarding postoperative bacteremia decrease

#### Protocol summary

##### Study aim

The aim of this study is the effect of bladder irrigation with 0.2% chlorhexidine before TURP in patients with Foley catheter regarding postoperative bacteremia decrease

##### Design

Study groups: Patients with benign prostatic hyperplasia  
Study: Randomized, blinded, sham controlled clinical trial with a parallel group  
The size of sample was 60, clinical trial phase: phase 3

##### Settings and conduct

Place of study: Alzahra Hospital, Isfahan  
These patients were randomly divided into two groups (case and control) according to random table.  
The study is a double blind clinical trial. The patient and the researcher did not know how to allocate placebo and drug for patients.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria were male gender, lack of sensitivity to latex, and age range between 50 to 80 years old.

##### Intervention groups

Intervention group: Chlorhexidine (as medicine) and control group: distilled water (placebo)

##### Main outcome variables

The amount of bacteremia and procalcitonin after surgery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180209038673N5**

Registration date: **2021-02-23, 1399/12/05**

Registration timing: **retrospective**

Last update: **2021-02-23, 1399/12/05**

Update count: **0**

##### Registration date

2021-02-23, 1399/12/05

##### Registrant information

###### Name

Robab Sheikhpour

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3623 5958

###### Email address

r.sheikhpour@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-12-22, 1398/10/01

##### Actual recruitment start date

2018-12-22, 1397/10/01

##### Actual recruitment end date

2020-02-20, 1398/12/01

##### Trial completion date

2020-02-20, 1398/12/01

##### Scientific title

The effect of bladder irrigation with 0.2% chlorhexidine before TURP in patients with foley catheter regarding postoperative bacteremia decrease

##### Public title

Bladder irrigation with 0.2% chlorhexidine before TURP in patients with Foley catheter regarding postoperative bacteremia decrease

##### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Male gender  
Lack of sensitivity to latex  
Age range between 50-80 years old

### Exclusion criteria:

Dissatisfaction of patients

## Age

From **50 years** old to **80 years** old

## Gender

Male

## Phase

3

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **60**

Actual sample size reached: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

We divide each referral into two groups using a randomized table. This table is a collection of numbers. Consider numbers from 1 to 30 for intervention A and numbers 31 to 60 for control B. Then let's move on one of the numbers and move in one of the preset directions and assign the numbers to one of the groups. Thus, patients are completely randomly divided.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this study, patients did not aware about prescription drugs (placebo and medication). Also, the person who provided these drugs to patients had no information about the allocation of patients to drug or placebo

## Placebo

Used

## Assignment

Parallel

## Other design features

In this study, 60 patients with Foley catheter were randomly divided into two groups of 30 patients. The bladder of patients in one group is rinsed with distilled water before surgery and the other group with chlorhexidine.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical committee of Isfahan University of Medical Sciences

##### Street address

Isfahan University of Medical Sciences, Hezar Jarib

street, Isfahan

#### City

Isfahan

#### Province

Isfahan

#### Postal code

81746-73461

#### Approval date

2018-09-25, 1397/07/03

#### Ethics committee reference number

IR. MUI.MED.REC 1397.073

## Health conditions studied

### 1

#### Description of health condition studied

Benign prostatic hyperplasia

#### ICD-10 code

N40.0

#### ICD-10 code description

Enlarged prostate without lower urinary tract symptoms

## Primary outcomes

### 1

#### Description

The amount of bacteremia after surgery

#### Timepoint

6 hours after surgery

#### Method of measurement

Measurement through blood culture

## Secondary outcomes

### 1

#### Description

Procalcitonin level

#### Timepoint

6 hours after surgery

#### Method of measurement

Serum measurement

## Intervention groups

### 1

#### Description

Intervention group: The bladder of patients in this group is rinsed with 0.2 percent chlorhexidine before surgery

#### Category

Treatment - Drugs

### 2

#### Description

Control group: The bladder of patients in this group is rinsed with distilled water before surgery

#### Category

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Alzahra hospital

**Full name of responsible person**

Hamed Jahangiri

**Street address**

Alzahra hospital, Soffeh Blvd, Shahid Keshvari Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3668 5555

**Email**

hamedjahangiri201999@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mojgan Mortazavi

**Street address**

Isfahan University of Medical Science, Hezar Jarib street, Isfahan

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**Phone**

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**Email**

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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**

Hamed Jahangiri

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Urology

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## Person responsible for scientific inquiries

### Contact

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Esfahan University of Medical Sciences

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Hamed Jahangiri

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Resident

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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**

Patients were not satisfied with the release of the data file.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not 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