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
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Iran (Islamic Republic of)
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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
Įladder 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

Isfehan

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mojgan Mortazavi

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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

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Hamed Jahangiri

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Urology

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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

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