

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The effect of Povidone-Iodine enema in the incidence of infectious complications following prostate needle biopsy in patients suspicious for prostate cancer and comparison with control group

#### Protocol summary

##### Summary

The aim of this clinical trial is to evaluate the effect of Povidone-Iodine enema in the incidence of infectious complications following prostate needle biopsy. 120 patients who are referred to the Urology department of Imam Reza Hospital, Mashhad due to abnormal prostate in digital rectal exam (DRE) or increase in prostate specific antigen (PSA) for biopsy of the prostate are divided randomly into two equal groups. After obtaining informed consent, the case group receive an intrarectal mixture of povidone-iodine and lidocaine gel before performing biopsy, while the control group receive only lidocaine gel. Rectal swab specimens obtain before and after biopsy and will send for culture. Patients are followed weekly up to 30 days for possible signs of infection or hospital readmission.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016092429935N1**

Registration date: **2017-11-13, 1396/08/22**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-11-13, 1396/08/22

##### Registrant information

##### Name

Seyedalireza Ghoreifinejadian

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3858 3885

##### Email address

ghoreifina@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2017-06-07, 1396/03/17

##### Expected recruitment end date

2018-11-29, 1397/09/08

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Povidone-Iodine enema in the incidence of infectious complications following prostate needle biopsy in patients suspicious for prostate cancer and comparison with control group

##### Public title

The effect of Povidone-Iodine enema in the incidence of infectious complications following prostate needle biopsy

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion Criteria: Men who refer to the Urology department of Imam Reza Hospital, Mashhad due to abnormal prostate in digital rectal exam (DRE) or increase in prostate specific antigen (PSA) for biopsy of the prostate , Obtaining informed consent  
Exclusion Criteria: No informed consent

##### Age

No age limit

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

**Street address**

Ghoreishi Building, Daneshgah St

**City**

Mashhad

**Postal code****Approval date**

2017-06-07, 1396/03/17

**Ethics committee reference number**

IR.MUMS.fm.REC.1395.645

**Health conditions studied****1****Description of health condition studied**

Acute prostatitis

**ICD-10 code**

N41.0

**ICD-10 code description**

Acute prostatitis

**Primary outcomes****1****Description**

infectious complications

**Timepoint**

every week to 30 days

**Method of measurement**

History and Physical exam

**Secondary outcomes****1****Description**

Rectal Culture

**Timepoint**

Before and after biopsy

**Method of measurement**

Rectal swab

**Intervention groups****1****Description**

Rectal enema with 50 cc mixture of Povidone-Iodine and lidocaine jelly before biopsy in case group

**Category**

Prevention

**2****Description**

Rectal enema with 50 cc lidocaine jelly before biopsy in control group

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Urology Department, Imam Reza Hospital

**Full name of responsible person**

Seyedalireza Ghoreifinejadian

**Street address**

Urology Department, Imam Reza Hospital

**City**

Mashhad

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Saeed Eslami

**Street address**

Ghoreishi Building, Daneshgah Street

**City**

Mashhad

**Grant name**

**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**  
Mashhad 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**  
Mashhad University of Medical Sciences

**Full name of responsible person**  
Seyedalireza Ghoreifinejadian

**Position**  
Assistant Professor of Urology

**Other areas of specialty/work**

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Assistant Professor of Urology

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**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*