

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The assessment of effect of local antiseptic on UTI in the cases of transrectal ultrasound-guided prostate biopsy

#### Protocol summary

##### Summary

Purpose of study: The assessment of effect of betadine on prevention of UTI after prostate biopsy; Study design: interventional; Method: The patients will be randomized into two groups. 1- In interventional group Betadine Vaginal Gel 10% (Povidone Iodine; 80g ) with Gavage Syringe is injected into the rectum and after 5 minutes prostate biopsy will be performed. 2- In control group patients will not receive betadine before prostate biopsy. 48h after the biopsy UA and UC will be obtained from patients and fever of the patients will be evaluated. The results of study in this two groups will be compared with together; Inclusion criteria: All patients that candidate for transrectal ultrasound-guided prostate biopsy who referred to Shahid Hasheminejad Hospital; Exclusion criteria: Unable to follow-up patients; Presence of abnormal UA and UC before Prostate biopsy; Unable to use local antiseptic; Previous prostatectomy; Intervention: Drug (Betadine); Target sample size: 300; Primary outcome measure: Acute prostatitis

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201201038605N1**  
Registration date: **2012-04-04, 1391/01/16**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-04-04, 1391/01/16

##### Registrant information

###### Name

Soodabeh Nikfarjam

##### Name of organization / entity

Tehran University of Medical Sciences (Paradise Hemmat)

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2219 2705

##### Email address

s\_nikfarjam@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2012-04-03, 1391/01/15

##### Expected recruitment end date

2012-10-06, 1391/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The assessment of effect of local antiseptic on UTI in the cases of transrectal ultrasound-guided prostate biopsy

##### Public title

The effect of betadine on prevention of UTI after prostate biopsy

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: All patients that candidate for transrectal ultrasound-guided prostate biopsy who referred to Shahid Hasheminejad Hospital; Exclusion criteria: Unable to follow-up patients; Presence of abnormal UA and UC before Prostate biopsy; Unable to use local antiseptic; Previous prostatectomy

**Age**

No age limit

**Gender**

Male

**Phase**

2-3

**Groups that have been masked**

No information

**Sample size**

Target sample size: **300**

**Randomization (investigator's opinion)**

Randomized

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

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

-

**Secondary Ids****1****Registry name**

-

**Secondary trial Id**

-

**Registration date**

empty

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

Ethics committee of Tehran University of Medical Sciences (Paradise Hemmat)

**Street address**

Medical school, near Milad hospital, Shahid Hemmat freeway

**City**

Tehran

**Postal code**

-

**Approval date**

2011-03-13, 1389/12/22

**Ethics committee reference number**

1372

**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**

acute prostatitis

**Timepoint**

48 hours after intervention

**Method of measurement**

U/A+U/C+Temperature of body

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

nothing

**Timepoint**

nothing

**Method of measurement**

nothing

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

Control:In this group without injection of betadine in the rectum prostate biopsy will be performed

**Category**

N/A

**2****Description**

intervention: Betadine Vaginal Gel 10% (Povidone Iodine; 80 g ) with Gavage Syringe is injected into the rectum and after 5 minutes prostate biopsy will be performed

**Category**

Prevention

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

Shahid Hasheminejad Hospital

**Full name of responsible person**

Dr Seyed Morteza Bagheri, Radiologist

**Street address**

Shahid Valinejad avenue, The North of Vanak square, Vali Asr street

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences (Pardise Hemmat)

**Full name of responsible person**

Dr Seyed Morteza Bagheri

**Street address**

Tehran University of Medical Sciences (Pardise Hemmat), near Milad Hospital, Shahid Hemmat freeway

**City**

Tehran

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

Yes

**Title of funding source**

Tehran University of Medical Sciences (Pardise Hemmat)

**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**

Tehran University of Medical sciences (Pardise Hemmat)

**Full name of responsible person**

Soodabeh Nikfarjam

**Position**

Student of Radiology

**Other areas of specialty/work****Street address**

Medical School, near Milad Hospital, Shahid Hemmat freeway

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## Person responsible for scientific 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*